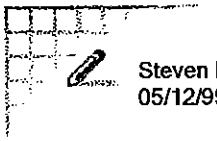
Exhibit 47

Todd Galles 05/03/99 08:06 PM

To: Debbie Bronstein/Dey_Labs/Merck-Gen/Merck@Dey_Labs
cc:
Subject: Ippy Pricingq

Kay Morgan of first Databank callesd to say they completed the GPI analysis and Alpharma, Dey and Roxane all fall within the generic classification. She told me it would be interesting to contact the HCFA or MediCal and look into whether there is a movement to mac reimbursement for Ippy now that there are three generics. If this were to happen then the playing field would once again be level We can also monitor and consider raising AWP. Todd



Steven Resnik
05/12/99 06:54 PM

To: Debbie Bronstein/Dey_Labs/Merck-Gen/Merck@Dey_Labs, Diane Morrill/Dey_Labs/Merck-Gen/Merck@Dey_Labs
cc:
Subject: Xopenex reimbursement

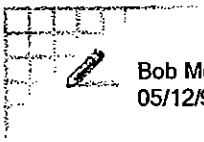
Debbie,

The situation regarding HCFA doesn't come as too much of a surprise based on what I have seen in the past. HCFA would not establish a new code until there was enough history demonstrating a demand for the product. This obviously created a classic catch 22 situation, because without a code healthcare professionals are unwilling to prescribe for the product. There are probably a number of ways to break this vicious cycle. One is to get MDs to demand the product regardless of the financial implications and generate enough submissions to Medicare to warrant a new code. Sepracor may need to pursue an alternate strategy, as their labelling wouldn't seem to support any meaningful clinical benefit justifying large numbers of physicians becoming strong supporters.

I don't anticipate as much of a problem for either DuoNeb or AccuNeb. As we discussed in the past, even at the HCFA rates for generics, prescribers of our products will still make money.

Steven

---------- Forwarded by Steven Resnik/Dey_Labs/Merck-Gen/Merck on 05/12/99 03:39 PM ----------



Bob Mozak
05/12/99 03:17 PM

To: Debbie Bronstein/Dey_Labs/Merck-Gen/Merck@Dey_Labs, Steven Resnik/Dey_Labs/Merck-Gen/Merck@Dey_Labs
cc:
Subject: Xopenex reimbursement

According to Harold Okocha of Healthscripts, Xopenex is now being reimbursed by HCFA(Medicare) exactly at the same rate as generic albuterol. That is .47 per vial..vs a cost of $ 1.58 per vial. What this means is that HCFA , has disregarded the high AWP of Xopenex, and considers it to be similar to the generic for payment purposes. Obviously, this will have significant impact on usage at least at the government level. Whether this will be the case with third party insurers is unclear.

Clearly, we need to get a good handle on this before setting price on both DuoNeb and AccuNeb

T

Dey, L.P.
2751 Napa Valley Corporate Drive
Napa, CA 94558
Tel.(707) 224-3200 Fax.(707) 224-0988

NOTICE OF PRICE CHANGE

December 15, 2003

Attention: Chain Buyer

Please accept this letter as formal notification of the price changes noted below.

Effective December 16, 2003, DEY is increasing the Wholesale Acquisition Cost (WAC) pricing on the following products:

DEY WAC Price Increases... Effective December 16, 2003				
Product	**NDC#**	**Carton Size**	**Old WAC $**	**New WAC $**
AccuNeb® (albuterol sulfate) Inhalation Solution 1.25 mg* / 3 mL *Potency expressed as albuterol, equivalent to 0.75 mg albuterol sulfate	49502-0693-03	25	$32.00	$33.28
AccuNeb® (albuterol sulfate) Inhalation Solution 0.63 mg* / 3 mL *Potency expressed as albuterol, equivalent to 1.5 mg albuterol sulfate	49502-0692-03	25	$32.00	$33.28
DuoNeb® (ipratropium bromide 0.5 mg/albuterol sulfate 3.0 mg*) Inhalation Solution, 3 mL * Equivalent to 2.5 mg albuterol base	49502-0672-30	30	$48.00	$49.92
DuoNeb® (Ipratropium Bromide 0.5 mg/Albuterol Sulfate 3.0 mg*) Inhalation Solution, 3 mL * Equivalent to 2.5 mg albuterol base	49502-0672-60	60	$96.00	$99.84

Please note... In lieu of Contract pricing, all Direct purchases will be invoiced at the new WAC price.

Direct purchases per customer will be limited to an additional thirty (30) day supply at the old price, and based on DEY's calculation of your most recent twelve (12) month average purchases. It is preferred that the additional thirty (30) day supply be made on a separate purchase order.

Any orders received on or after December 16, 2003 will be processed with the new price. Billing adjustments will be issued as a credit memo. Please contact your DEY Representative who can provide you with your purchasing options.

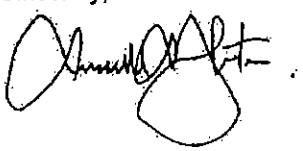
An Affiliate of EMD, Inc.

Effective December 16, 2003, DEY is increasing the Average Wholesale Price (AWP) on the following products:

DEY AWP Price Increases... Effective December 16, 2003				
Product	**NDC#**	**Carton Size**	**Old AWP $**	**New AWP $**
AccuNeb® (albuterol sulfate) Inhalation Solution 1.25 mg* / 3 mL *Potency expressed as albuterol, equivalent to 0.75 mg albuterol sulfate	49502-0693-03	25	$40.00	$41.60
AccuNeb® (albuterol sulfate) Inhalation Solution 0.63 mg* / 3 mL *Potency expressed as albuterol, equivalent to 1.5 mg albuterol sulfate	49502-0692-03	25	$40.00	$41.60
DuoNeb® (ipratropium bromide 0.5 mg/albuterol sulfate 3.0 mg*) Inhalation Solution, 3 mL * Equivalent to 2.5 mg albuterol base	49502-0672-30	30	$60.00	$62.40
DuoNeb® (Ipratropium Bromide 0.5 mg/Albuterol Sulfate 3.0 mg*) Inhalation Solution, 3 mL * Equivalent to 2.5 mg albuterol base	49502-0672-60	60	$120.00	$124.80

Please contact our Sales Department at 1-800-755-5560 if you need additional information. You may place an order by calling our Order Department at 1-800-527-4278.

Sincerely,



Russell R. Johnston
Manager, Sales/Marketing Services

H9-373-00

Exhibit 48

Veda Litton
04/24/2002 04:35 PM

To: Raje Dhillon/Dey_Labs/Merck-Gen/Merck@Dey_Labs
cc:
Subject: MCNAM Monthly Reports 4-24-02

---------- Forwarded by Veda Litton/Dey_Labs/Merck-Gen/Merck on 04/24/2002 01:34 PM ----------

Adam Kopp 04/24/2002 05:25 AM

To: Jerry Crank/Dey_Labs/Merck-Gen/Merck@Dey_Labs
cc: Kevin Shawver/Dey_Labs/Merck-Gen/Merck@Dey_Labs, Veda Litton/Dey_Labs/Merck-Gen/Merck@Dey_Labs
Subject: MCNAM Monthly Reports 4-24-02

Jerry,

Attached are my MCNAM reports for April. I am turning these reports in a few days early since I will be in Napa at the end of this week. Note that the HHC, LTC reports do not have updated sales data since I have not received current sales reports as of 4-24.



AKopp Activity Monthly 4-02.d AKopp Monthly Issues 4-02.d AKopp Top 10 HC-LTC 4-02.


AKopp Top 10 MC-PBM 4-02. MCO-PBM Ranking ABC 4-02

Enjoy.

Adam

I N T E R
O F F I C E

DEY, L.P.
MEMORANDUM

TO: Jerry Crank CC: Kevin Shawver

FROM: Adam Kopp

DATE: April, 24, 2002

RE: Monthly Issues Report

Key Issues: Market, Customers, Products

Nephron is aggressively marketing to the HHC market. The outfit doing the presentations is RxElite from Lake, TX. They are offering pricing of .13 for albuterol and .22 for ipratropium. This is very misleading to the HHC market because Nephron has lowered their AWP by 40% which makes it difficult to gain favorable reimbursement through Medicaid.

Home Reach HHC in Worthington, OH is using DuoNeb on a limited basis. Willis Triplett at Home Reach is upset with Dey's decision to market AccuNeb. Thinks it is a horrible product. They had a letter sent to them from Diane Morrill promoting AccuNeb. I don't know if Willis has contacted Diane.

Potential Customers If Dey did this:

If Dey lowered the cost to the existing HHC customers using DuoNeb , Dey may gain additional business since HHC is cautiously dispensing DuoNeb because the profits are not as high as they were when they were dispensing 2 UD. Many HHC outfits currently dispensing DuoNeb are also dispensing 2 UD to help off set the low reimbursement they are receiving from DuoNeb. Also, the small independent HHC say they need to see DuoNeb pricing at about .80 p/UD to convert to DuoNeb.

Maybe once a large HHC ie..Lincare, Apria converts to DuoNeb, the smaller HHC will convert due to pressure of losing business, even if the price isn't at .80p/UD

Key Regional Issues Clinical/Institutional

I need an updated list showing what RSMs are responsible for the state of Tennesee. It seems that there are possibly 4 clincal RSMs and 2 ASMs managing Tennessee. With the recent realignment I want to make sure all managers are being copied on all reports for Tennessee.

Medicaid Update

North Carolina State Medicaid has a new Pharmacy Consultant. Charman Leiwand has replaced Benny Ridout who left to go to work for the Brand Pharma Manf. Assoc. as a lobbyist. NC pharmacists are seeing their dollars cut by the state in an effort to lower drug costs. The pharmacists feel that the cuts shouldn't be made to the pharmacists but to the structure of the drug program.

Program Needs

Can the MCNAMs get a list of all Dey -RDI accounts so we are aware of who we shouldn't target.

Communication Plan/Issues

The monthly reports the MCNAMs are sending to the ASMs/RSMs to be sent to the field force have been helpful according to the TAMs. The KAMs are now requesting to receive the HMO coverage report and updates on HHC with the purchasing patterns for the select HHC they are now calling on.

Training Issues

Need to train the TAMs on the importance of gaining physician champions to use Prior Approval forms, when Dey Brands are not on formulary. The use of

the PA forms generates utilization data, requests, which in turn, give the pharmacy directors of the MCOs an idea of how physicians are viewing the medications. Utilization numbers can only help gain better formulary coverage.

Other

My number of monthly calls are off slightly because I was on vacation for the first week of April.

Exhibit 49

Calculation of Damages and Penalties for the State of Montana

Declaration of Raymond S. Hartman

I. Introduction and Overview

1. My name is Raymond S. Hartman. I am Director and President of Greylock McKinnon Associates (GMA), an economic consulting and litigation support firm located in Cambridge, Massachusetts. Since I have previously described my qualifications to this Court, I will not repeat them here.

2. I have been asked by Counsel to the State of Montana to review the Complaint in this matter;[1] to review the allegations regarding fraudulent pricing practices on the part of Defendants; and to describe the formulaic methodologies I would use to calculate both the damages to the State and its consumers if the alleged fraudulent pricing practices are proved and the penalties to the Defendants arising from those fraudulent practices.

3. The fraudulent pricing practices specifically alleged of twenty-one Defendant drug manufacturers[2] are characterized as the "AWP Inflation Scheme."[3] Through the alleged "AWP Inflation Scheme" (or "AWP Scheme"), Defendant manufacturers fraudulently increased the AWPs of selected drugs (denoted by NDCs) above the provider acquisition costs (ACs) for which the AWPs were a market signal.[4] Defendants reported the inflated AWPs to the standard national price compendia (*First DataBank (FDB), Red Book* and *Blue Book*), and the industry based reimbursement amounts on those AWPs. Since providers acquired the drugs at acquisition cost (AC) while payors (Medicare, Medicaid, private Third-Party Payers (TPPs), and consumers) paid for the drugs at reimbursement rates based on the AWPs, the increased "spreads" (AWP – AC) caused by the AWP Scheme increased the profits earned by the providers of the drugs (pharmacies, physicians) at the expense of the payors. The increased profits induced providers to move market share of the relevant drugs, the *raison d'etre* of the AWP Scheme to the drug manufacturers.[5]

---

[1] State of Montana's Second Amended Complaint, *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, United States District Court for the District of Massachusetts, August 1, 2003 (hereafter, *Complaint*).

[2] Identified and discussed in detail in the *Complaint* in ¶¶ 214-602. I have been instructed by Counsel to exclude the GSK Group from my analysis.

[3] *Complaint*, ¶¶ 5-10.

[4] Market reliance upon reported AWPs is discussed in ¶¶ 169-172 of the *Complaint*.

[5] A more complete discussion of the fraud and its market effects are developed in ¶¶ 173-213 of the *Complaint*.

4. The relevant Plaintiffs in this matter for whom damages are alleged include, but are not limited to,[6] the following:

a) The State of Montana

- For pharmaceutical reimbursements under Medicaid (see *Complaint*, ¶¶ 15, 159-163)
- For pharmaceutical reimbursements under Medicaid for "dual eligibles" under Medicare (see *Complaint*, ¶ 158)
- For pharmaceutical reimbursements by State employees (see *Complaint*, ¶ 16)
- For pharmaceutical payments made by State agencies (see *Complaint*, ¶ 17)

b) Montana consumers

- Those consumers making drug coinsurance payments under Medicare Part B (see *Complaint*, ¶ 20)
- Those consumers making coinsurance payments under a private third-party payer plan (see *Complaint*, ¶ 20)
- Those consumers without prescription drug insurance coverage making payments out of pocket (see *Complaint*, ¶ 2).

5. The claims for damages and/or financial penalties made by Plaintiffs include, but are not limited to, the following:

a) Restitution for losses incurred by Montana residents as a result of the AWP Scheme (*Complaint*, ¶¶ 654-660);

b) Restitution of the losses suffered by the State of Montana as a result of the AWP Scheme and recovered as civil penalties for deceptive acts or practices in violation of Mont. Code Ann. §§ 30-14-103 (*Complaint*, ¶¶ 662-667);

c) Recovery of inflated Medicaid reimbursements resulting from fraudulent reporting of inflated AWPs, in violation of Mont. Code Ann. § 53-6-160(1) (*Complaint*, ¶¶ 676-678);

d) Payment of a claim for forfeiture, civil penalties, double damages and legal costs for each violation of Mont. Code Ann. § 17-8-231 under the AWP Scheme (*Complaint*, ¶¶ 681-691); and

e) Payment of punitive damages to the State of Montana (*Complaint*, ¶ 693).

6. To date, Defendants have provided incomplete data and insufficient guidance to fully interpret the data that they have provided to allow me to appropriately calculate damages for all the claims identified above. For example, insufficient data and/or insufficient data description were provided by Defendants to appropriately calculate all

[6] Since I have not had sufficient time to fully analyze all discovery materials, there may be additional Plaintiff groups and additional drugs subject to damage calculations that I will be able to address, if asked to, in a Supplementary Declaration. I anticipate that those damage calculations will make use of formulaic methods analogous to those put forward here.

damages for all injured parties alleged under the AWP Inflation Scheme. I develop methodologies for calculating damages alleged under the AWP Scheme and use them where the data permits. However, given my inability to fully analyze the data submitted by Defendants, I have been instructed by Counsel to develop alternative methodologies that allow me to calculate aggregate penalties arising from the violations alleged in the *Complaint,* in the absence of a complete production of data. I reserve the right to supplement my analyses once sufficient data become available. Given the absence of complete information to calculate all damages and penalties for all Plaintiffs injured under the AWP Inflation Scheme, the damages presented in this Declaration are conservative.

7. My Declaration proceeds as follows. In Section II, I conduct the analysis to develop the formulaic methodologies that can be used for calculating the damages and penalties induced by Defendants' conduct. In Section III, I discuss the measurement of specific components of selected formulaic methodologies and the implementation of those methodologies for those groups for which damages and penalties can be calculated. In Section IV, I implement my formulaic methodologies for those drugs, Defendants, and damage/penalty measures for which data are available. Attachment A lists additional materials relied upon and not identified in my declarations previously submitted in this matter.

II. Analysis

A. The Purpose of the Medicaid and Medicare Statutes

8. The Medicaid drug program and the federal and state initiatives to effectuate it have been designed to implement cost-based drug reimbursement. The legislation and regulation enabling the Medicaid drug program have encouraged states to base their payments on Estimated Acquisition Cost (EAC), as reflected in an early Health Care Financing Administration (HCFA) memorandum:

> "The intent of the final Medicaid regulations on drug payment is to have each state's estimated acquisition cost as close as feasible to the price generally and currently paid by the provider. The states are, therefore, expected to see that their ingredient cost levels are as close as possible to actual acquisition cost."[7]

As part of the process, over time states have come to require the amount allowed (AA) for Medicaid reimbursement be **the lesser of** the possible measures of cost – the EAC, the Federal Upper Limit (FUL), the state maximum allowable cost (MAC), the

[7] HHS Action Transmittal, HCFA-AT-77-113 (MMB), December 13, 1977. Subject: "Title XIX, Social Security Act: Limitation on Payment or Reimbursement for Drugs: Estimated Acquisition Cost (EAC)." Indeed, in 1976 the Department of Health and Human Services (HHS) implemented drug reimbursement rules articulating upper limits for payments by Medicaid and other programs (45 CFR Part 19). The rules were designed to ensure that the federal government acts as a cost conscious purchaser of drugs. Of the Federal programs involved, these rules have the greatest impact on the Medicaid program. In 1983, the HHS began reviewing the department's drug reimbursement regulations. The revised regulations were published on July 31, 1987 (52 Fed. Reg. 28648).

Usual & Customary amount (U&C) charged by a pharmacy, and the amount billed. Which of these alternative prices has been relevant has depended upon whether the drug being reimbursed is a single-source or multi-source drug.

a) For single-source drugs, State Medicaid agencies have focused primarily on determining the EAC (and the dispensing fee for the drug), since EAC is invariably less than U&C and the amount billed. Expecting that the AWP provided a reasonable signal for ASPs and EACs,[8] "[t]he EAC for most States is [has been] calculated by using the average wholesale prices (AWP) for a drug less a percentage discount."[9]

b) For multi-source drugs, FUL and MAC are relevant. Once a sufficient number of generic drugs have launched, Medicaid can reimburse for drugs under the Federal Upper Limit (FUL) program. FUL can be established only if all versions of a drug product have been classified as therapeutically equivalent (A-rated) by the FDA in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations" and at least three suppliers are listed in the current editions of published national compendia. However, FUL is still linked to the AWPs of the related drugs,[10] and this linkage usually limits its ability to constrain prices increases.[11]

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[8] Properly measured, the ASP to a particular group of providers is the EAC of that group of providers. I have addressed the equivalence of ASP and EAC in ¶ 10.b) of my September 3, 2004 Declaration in Support of Class Certification in the MDL AWP litigation; in ¶¶ 42, 47 & 49 and footnotes 21 and 75 of my December 16, 2004 Rebuttal Declaration in the MDL litigation; and in Attachment K to my December 15, 2005 Declaration on Liability and Calculation of Damages in the MDL litigation.

[9] See U.S. Department of Health and Human Services, OIG, *Medicaid Pharmacy - Actual Acquisition Cost of Generic Prescription Drug Products*, A-06-01-00053, March 2002, p. 1. The report continues (p. 1), "The AWP is the price assigned to the drug by its manufacturer and is compiled by the Red Book, First DataBank, and Medi-Span for use by the pharmaceutical community. Prior to 1984, most States used 100 percent of AWP for reimbursement of acquisition costs." After 1984, a variety of discounts off AWP were paid by manufacturers, reducing the retailer acquisition cost. These discounts were reflected in the reimbursement amounts allowed. For examples, by 1997 the OIG found that the average discount below AWP to retailers was 18.30% for brand name drugs; by 2002, the OIG found that the average discount below AWP to retailers was 22%. See ¶¶ 21-24 of Attachment D to my September 3, 2004 MDL Declaration in Support of Class Certification. This observed discount was reflected in the percentage off AWP incorporated into state Medicaid reimbursement formulae generally.

See also Stephen W. Schondelmeyer and Marian V. Wrobel, "Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices, Final Report," Abt Associates Inc., prepared for Center for Medicare and Medicaid, 2004, p. 4; the National Pharmaceutical Council, "Pharmaceutical Benefits Under State Medical Assistance Programs," 2000, p. 4-51; and Table D.1 of my September 3, 2004 MDL Declaration is Support of Class Certification, which presents each state's Medicaid reimbursement formula relative to AWP as of 2004.

[10] For example, under 42 CFR 447.332 (b), the FUL price is required to be set at an amount equal to 150 percent of the published price (in *Blue Book*, *Medi-Span* and/or the *Red Book*) for the least costly generic substitute (as purchased by pharmacists in quantities of 100 units (tablets or capsules)). There seems to be conflicting information as to whether FUL is set at 150% of the lowest AWP or at 150% of other prices that are published in national compendia. For example, one OIG report states that it is set off of AWP: "The upper limit amounts are based on 150 percent of AWP for the lowest priced generic equivalent." See *Medicaid Pharmacy – Actual Acquisition Costs of Generic Prescription Drug Products*, Office of Inspector General, Department of Health and Human Services, March 2002, A-06-01-00053 at p. 4. However, in a

9. The Medicare Program has limited its drug reimbursement primarily to physician-administered drugs under Part B. Medicare has also been designed to limit the amounts allowed as reimbursement to the costs incurred by providers (physicians) in acquiring the relevant drugs. In Attachment D to my September 3, 2004 MDL Declaration in Support of Class Certification, I summarize some history of the Medicare Program and the fact that its original approach to reimbursement was cost-based; see ¶¶ 5-7 of that Attachment D. In footnotes 13-14 to my December 15, 2005 MDL Declaration on Liability and the Calculation of Damages, I present the formulae for reimbursement rates under Medicare for physician-administered drugs over time. The criteria consistently involve the lesser of the acquisition cost of the physician and AWP less some amount.

10. Hence, Montana's procedures for reimbursement of drug-related claims under Medicaid and Medicare have been designed to guarantee that the amount allowed as reimbursement approximates as nearly as possible the acquisition costs incurred by the providers of those drugs.

B. Implications of the AWP Inflation Scheme for Drugs Reimbursed Under Medicaid and Medicare

11. To the extent that the alleged AWP Scheme was effectuated by Defendants, the Scheme would have revealed itself in an "excessively" large spread or deviation between an inflated AWP and the acquisition cost of (or sale price to) the relevant providers, for which the AWP is generally taken as a signal.[12] This inflation affected all purchasers of the relevant pharmaceuticals. However, I focus here on the effects of reimbursement under Medicaid and Medicare.

12. As noted in the *Complaint* (at ¶ 170), the Office of the Inspector General (OIG) of the Department of Health and Human Services (DHHS) affirms that the "government sets reimbursement with the expectation that the data provided are complete and accurate." Specifically,

---

CMS response by Mark McClellan to another OIG report (*How Inflated Published Prices Affect Drugs Considered for the Federal Upper Limit List*, Office of Inspector General, Department of Health and Human Services, September 2005, OEI-03-05-00350), he states: "Federal regulation (42 CFR Section 447.332) requires the FUL amount to be 150 percent of the published price for the least costly therapeutic equivalent using data from all available national compendia. The FUL system selects the lowest price of average wholesale price (AWP), wholesale acquisition cost (WAC), or direct price (DP), as reported by the national compendia, to arrive at the FUL price" (at p. 13). Invariably, however, EAC is less than 150% of any of these list prices.

[11] Since Montana does not have a state MAC, this price alternative does not limit Medicaid reimbursement rates. See Table D.1 of Attachment D to my September 3, 2004 Declaration in Support of Class Certification.

[12] Methods for calculating overcharge damages induced by the "AWP Inflation Scheme" have been identified and implemented previously in the MDL AWP matter and in the Connecticut AWP matter. See the Declaration of Raymond S. Hartman in Support of Class Certification, September 3, 2004 and the Declaration of Raymond S. Hartman in Support of Plaintiffs' Claims of Liability and Calculation of Damages, December 15, 2005, both *In re Pharmaceutical Industry Average Wholesaler Price Litigation*; and Calculation of Damages to Connecticut for State Expenditures under the Medical Assistance Programs, Declaration of Raymond S. Hartman, *State of Connecticut v. Dey, Inc., et al.*, January 19, 2006 and Expert Disclosure, Raymond S. Hartman, *State of Connecticut v. Dey, Inc., et al.*, November 1, 2005.

"Many federal and state health care programs establish or ultimately determine reimbursement rates for pharmaceuticals, either prospectively or retrospectively, using price and sales data directly or indirectly furnished by pharmaceutical manufacturers. The government sets reimbursement with the expectation that the data provided are complete and accurate. The knowing submission of false, fraudulent, or misleading information is actionable. …

Where appropriate, manufacturers' reported prices [therefore] should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers. Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products. … Underlying assumptions used in connection with reported prices should be reasoned, consistent, and appropriately documented, and pharmaceutical manufacturers should retain all relevant records reflecting reported prices and efforts to comply with federal health care program requirements."[13]

13. Defendants are alleged to have distorted the pricing information upon which government programs rely, with the specific intention of artificially inflating spreads.[14]

"The 'spread' is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer. In many situations under the federal programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who purchase the product for their own accounts and thereafter bill the federal health care programs will be reimbursed. To the extent that a manufacturer controls the 'spread', it controls its customer's profit.

Average Wholesale Price (AWP) is the benchmark often used to set reimbursement for prescription drugs under the Medicare Part B program. For covered drugs and biologicals, Medicare Part B generally reimburses at '95 percent of average wholesale price.' …Similarly many state Medicaid programs and other payers base reimbursement for drugs and biologicals on AWP. Generally, AWP or pricing information used by commercial price reporting services to determine AWP is reported by pharmaceutical manufacturers.

If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike *bona fide* discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller's immediate customers from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. In other words, it is illegal for a

[13] US DHHS, OIG, *Compliance Program Guidance for Pharmaceutical Manufacturers*, April, 2003. pp. 11-12; cited in *Complaint*, ¶ 170.

[14] *Ibid.*, pp. 26-27; cited in *Complaint*, ¶ 171.

manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the 'spread' to induce customers to purchase its product."

14. For purposes of this discussion, I use ASP to denote the average sales price to the relevant class of trade (e.g., retail pharmacies, physicians), which is equivalent to the acquisition cost (AC) of that class of trade when properly measured (see footnote 8 above). While the "spread" is often measured using the AWP and the ASP,[15] it can also be measured as the "spread" or difference between the reimbursement rates that are related to the AWPs and the ASPs which measure provider acquisition costs.

For purposes of this analysis, I make use of the latter definition of spread. I focus upon the spreads between the amounts allowed to providers as drug reimbursement under the Medicaid and Medicare Programs relative to costs at which those providers acquire those drugs. I have been advised by Counsel that if these spreads are larger than allowed by the relevant statute(s), the AWP Scheme led to excessive reimbursement for drug claims. I can calculate the overcharge damages arising from that artificial AWP inflation. I can also determine whether the amounts allowed as reimbursement constitute an excessive amount deceptively charged to and/or falsely claimed in Medicaid and Medicare reimbursement claims.

C. Calculation of Overcharge Damages Under Medicaid and Medicare Arising from the AWP Inflation Scheme

15. Under Medicaid and Medicare, the amount allowed (AA) as reimbursement is related formulaically to the actual (and allegedly artificially inflated) AWP.[16] Specifically, for a given claim, AA = "AWP – x%" + df[17] = (100% – x%)*AWP + df = p*AWP + df for any x%,[18] where the dispensing fee is designated as df and where p =

[15] For example, it can be expressed as (AWP – ASP)/ASP, (AWP – ASP)/AWP, AWP/ASP, or (AWP – ASP). I have addressed these other formulations in my earlier MDL analyses before this Court and in my Connecticut analysis.

[16] As discussed below, the methodology accommodates the reliance upon FUL, U&C or amount billed when they are the basis for AA in the claims data.

[17] Note that I use industry nomenclature to designate reimbursement off AWP as "AWP less some percent (x%)", which really means (100% - x%)*AWP.

[18] According to CMS materials dated June 2004, the reimbursement formulation for self-administered drugs in Montana is AWP – 15% under Medicaid, for both branded and generic drugs. The dispensing fee (df) is $4.70. According to that source, Montana has no MAC; see Table D-1, Attachment D to my September 3, 2004 MDL Declaration in Support of the Certification of Class. From 1991 through June 2002, I understand that the reimbursement formula was AWP – 10%. Note that the *Complaint*, at ¶ 162, suggests that Montana does have a MAC, which diverges from the CMS information in my Table D-1. While this divergence may suggest the need for further scrutiny, if the claims are based upon a state MAC, they will be reflected in the average AA calculated from the claims data.

The amount allowed under Medicare is AWP – x%, where x% is designated over time as delineated in footnote 13 to my December 15, 2005 MDL Declaration on Liability and the Calculation of Damages.

(100 – x)%.[19] Denote the but-for allowed amount as $AA^{but\text{-}for}$.[20] The difference between AA and $AA^{but\text{-}for}$ can be used to calculate overcharge damages as follows.

16. For each year of the period alleged to be subject to the AWP Inflation Scheme, State claims data summarize total number of claims and total dollar reimbursements paid by the State under the Medicaid Program and for drugs reimbursed for dual-eligibles (payment of Medicare supplemental insurance amounts (20%) for physician-administered drugs) by NDC and/or by J-Code. For a given NDC or J-Code, those data would reflect the following:

(1a) Actual Reimbursements = $\Sigma_i AA_i * q_i = \Sigma_i (p*AWP + df)_i * q_i = (p*AWP + df)*Q$,

where Actual Reimbursements is the total dollar amount of claims paid in a given year; Σ_i is the summation of the allowed amount$_i$ (AA_i) times the number (q_i = quantity$_i$) of claims (alternatively the units reimbursed per claim) reimbursed at AA_i; and Q is the total claims or total units reimbursed by the State at an average allowed amount of AA^{avg} = (p*AWP + df).[21]

Had these reimbursements been made at the but-for allowed amount per claim i ($AA^{but\text{-}for}{}_i$), the total reimbursements that should have been paid by the State in a given year would have been,

(1b) But-For Reimbursements = $\Sigma_i AA^{but\text{-}for}{}_i * q_i = (AA^{but\text{-}for\text{-}avg})*Q$,

where the total number of units is assumed to be the same in the but-for and actual worlds.

Having calculated But-For Reimbursements, the damages to the State for reimbursements for drug j of Defendant k are

(1c) Overcharge Damages$_{jk}$ = Actual Reimbursements$_{jk}$ – But-For Reimbursements$_{jk}$

$$= \Sigma_i AA_i * q_i - \Sigma_i AA^{but\text{-}for}{}_i * q_i$$

$$= (AA^{avg} - AA^{but\text{-}for\text{-}avg})Q.$$[22]

17. Aggregate overcharge damages (1c) can be calculated for all units of drug j sold by Manufacturer k and reimbursed by the State as a whole for the Damage Period as a whole; alternatively, it can be calculated for some subset of NDCs of drug j for some subset of State reimbursements for some sub-period of the Damage Period. The use of Equation (1c) is particularly straightforward. The State has data for Actual

[19] Of course, in the actual calculations the percentages are denoted as follows: 100% = 1.00; 15% = 0.15; 10% = 0.10; etc.

[20] Which would be related to a but-for non-inflated AWP as $AA^{but\text{-}for} = AWP^{but\text{-}for} - x\% + df = (100\% - x\%)*AWP^{but\text{-}for} + df = p*AWP^{but\text{-}for} + df$.

[21] The state data summarize reimbursement for all claims. Hence, if some claims are determined by FUL, U&C or the amount billed (all of which I understand are related to AWP), the AA for those claims are specific to that definition and AA^{avg} reflects those claims.

[22] And if we make use of a but-for non-inflated AWP, Overcharge Damages$_{jk}$ = $(p*AWP + df)*Q - (p*AWP^{but\text{-}for} + df)*Q$.

Reimbursements$_{jk}$ for all relevant drugs and Defendant manufacturers, for the relevant Damage Period, for Medicaid and Medicare program reimbursements. The But-For Reimbursements are determined by statute.

D. Calculation of Penalties for Deceptive Practices and False Claims Under the AWP Inflation Scheme

18. Under Count II (¶¶ 662-667) of the *Complaint,* the claim is made for restitution of losses suffered by the State of Montana as a result of the AWP Scheme. Defendants conduct as alleged constitutes deceptive acts or practices in violation of Mont. Code Ann. § 30-14-103 for those transactions in which the AWP was inflated; and for which Defendant manufacturer failed to disclose material facts that the AWP exceeded the average of the wholesale price based upon a good faith and reasonable estimate; and that the Defendant manufacturer knowingly made false representations by representing that the AWP was an accurate reflection of the average wholesale price. Pursuant to Mont. Code Ann. § 30-14-142(2), the *Complaint* states that the Court can assess civil penalties of $1,000 from each defendant for each willful violation of Mont. Code Ann. § 30-14-103.

19. Under Count IV (¶¶ 682-691) of the *Complaint*, a claim for forfeiture, civil penalties, double damages and legal cost pursuant to Mont. Code Ann. § 17-8-231 is made in ¶ 691. Accordingly, it is claimed (¶ 691.C) each defendant must forfeit the entirety of their claims and pay (i) civil penalties of $2,000 per false claim, (ii) double the damages sustained by the State as a result of the false claim, and (iii) the State's legal costs incurred in connection with this action.

20. I have been directed by Counsel to assume that penalties of $3,000 can be assessed for each claim submitted for reimbursement under Medicaid and Medicare that was subject to a deceptive practice and was false.[23] The number of such claims can be calculated as follows.

21. As noted in ¶ 8 above, the allowed amount (AA) under Medicaid is to be the lesser of {the EAC, the Federal Upper Limit (FUL), the state maximum allowable cost (MAC), the Usual & Customary amount (U&C) charged by a pharmacy, or the amount billed}. Likewise, as noted in ¶ 8 above, EAC is invariably the lowest price.

Hence, for any drug reimbursed under Medicaid, I have been instructed by Counsel that liability occurs as a matter of law if $AA_{jk} > EAC_{jk}$. Furthermore, as discussed above (see footnote 8), $EAC_{jk} = ASP_{jk}$ to the relevant group of providers (pharmacies, physicians). For self-administered drugs reimbursed under Medicaid, j denotes the NDC of the drug and k denotes the Defendant. For physician-administered drugs, j denotes the NDC or the J-Code and k denotes the Defendant.

22. I have been provided with information from the State sufficient to calculate AA_{jk} by claim, net of the dispensing fee. While I received from Defendants a variety of data

[23] My methodology focuses upon accurately calculating the number of complaints that were deceptive and false. Should I receive alternative direction from the Court regarding the amount of the penalty to be assessed per false and deceptive claim, the calculation of aggregate penalties will be very easy to revise to accommodate those alternative directions. The revised calculation is simple arithmetic.

sets summarizing (to varying degrees of completeness) invoice information, rebates information and other accounting information, I have not received from Defendants sufficient explanation and clarification of these data to accurately calculate the ASP_{jk} by NDC and/or J-Code for most drugs and most Defendants in this matter. Indeed, the data that I have been able to use to analyze liability using ASPs have been developed as part of the MDL AWP litigation addressing the Track 1 Defendants and the Connecticut AWP litigation.

Given this limited ability to make use of discovery materials, I have developed a method to make use of the existing information to draw conclusions regarding liability. Specifically,

a) For claims for reimbursement for single-source self-administered drugs, I conclude liability as follows:

- For those NDCs for which I have ASPs and for which AA > ASP = EAC, I conclude that AA fraudulently exceeds EAC.
- Since the Amount Billed and the U&C > EAC, EAC will be the lesser of the alternative reimbursement bases.[24]
- AWP – (16.6%-20%)[25] = WAC
- I understand that the retail acquisition costs (RAC) is approximately equal to WAC and indeed may be slightly less {that is, RAC (EAC) < WAC}, perhaps 1-2% of AWP.[26] To be conservative, I assume that RAC = EAC ≈ WAC.[27]
- Using the upper bound of these discounts off AWP, if AA > AWP – 20%, AA exceeds EAC.
- Using the lower bound of these discounts off AWP, AA > AWP – 16.6%, AA exceeds EAC.
- Absent a measure of ASP, I let the threshold for liability be AA > AWP – 20%. For sensitivity analysis, I let the threshold for liability be AA > AWP – 16.6%. In each case, if AA exceeds the threshold I conclude AA fraudulently exceeds EAC.

b) For claims for reimbursement for multi-source self-administered drugs, I conclude liability as follows:

- For those NDCs for which I have ASPs and for which AA > ASP = EAC, I conclude that AA fraudulently exceeds EAC.
- Since the Amount Billed and the U&C > EAC; since FUL > EAC; and since Montana does not have a state MAC; EAC will be the lesser of the alternative reimbursement bases.
- Evidence demonstrates that EACs (i.e., ASPs or RACs) < AWP – (16.6%-66%)[28] over the period 1991-2002.

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[24] The U&C is the "walk-in" price paid by uninsured cash payers; it is usually ≈ AWP.

[25] These discounts off AWP are equivalent to spreads of 20%-25% above WAC. For example, if AWP – 20% = WAC; then AWP (100%-20%) = .80*AWP = WAC; and AWP = 1.25 WAC or WAC + 25%.

[26] See footnote 9 above.

[27] This understanding is corroborated by Defendants' Experts; see footnote 8 above.

- Absent a measure of ASP, and given the fact that I have not made a complete enough analysis of the pattern of increasing discounts off AWP over the Damage Period, I conclude that a reasonable threshold for liability for the Damage Period as a whole is AA > AWP – 25%. If AA exceeds this threshold, I conclude AA fraudulently exceeds EAC.
- However, in my calculations in Section IV below, I bound this reasonable threshold by allowing the threshold to be AWP – 20% and AWP – 66%.

c) For claims for physician-administered drugs reimbursed under Medicaid, I conclude the following:

- For those drugs for which I have ASPs and AA > ASP = EAC, I conclude that AA fraudulently exceeds EAC. The ASP may be delineated by NDC or J-Code. Given the time consuming process of performing the cross-walk for multi-source physician-administered drugs reimbursed by J-Code, I do not analyze liability for physician-administered drugs once they go generic, even if I have ASP data for a generic drug of a Defendant. Note that this exclusion will make my calculation of penalties conservative.
- Since the Amount Billed, the U&C and FUL > EAC; and since Montana does not have a state MAC; EAC will be the lesser of the alternative reimbursement bases.
- Evidence demonstrates that for single-source drugs, physician acquisition cost (PAC) is at most equal to WAC and often much less (i.e., PAC < AWP – (20%-75%).
- Absent a measure of ASP, and given the fact that I have not made a complete enough analysis of the pattern of increasing discounts off AWP over the Damage Period, I conclude that a conservative threshold for liability for the Damage Period as a whole is AA > AWP – 25%. If AA exceeds this threshold, I conclude AA fraudulently exceeds EAC.
- However, in my calculations in Section IV, I bound this threshold by allowing the threshold to be AWP – 20% and AWP – 66%.
- Because Montana began to rely upon Medicare data for AWPs for Medicaid-reimbursed drugs dispensed under J-Codes and because Medicare shifted in 2005 to reimbursement based upon ASP, I do not include any reimbursement claims for 2005.

[28] Since evidence indicates that EAC < 16.6%-20% for brand name drugs, it is well known that the discount off AWP for generic drugs will be greater than 16.6% - 20%. For example, by 1997, the OIG found that the average discounts below AWP at retail were 42.45% for generics. By 2002, OIG found these discounts from AWP to be even deeper, approximately 66%. See ¶¶ 21-24 of Attachment D to my September 3, 2004 MDL Declaration in Support of Class Certification. Both of these OIG reports used a sampling of states. The earlier report used a sample of ten states and the District of Columbia; the later report used a sample of 8 states. Montana was one of the states chosen in both of the samples. See *Medicaid Pharmacy – Actual Acquisition Costs of Generic Prescription Drug Products*, Office of Inspector General, Department of Health and Human Services, March 2002, A-06-01-00053.

23. For the analysis of Medicaid reimbursement for dual-eligible Medicare claims, the available medical claims summarize reimbursement for the 20% Medicare coinsurance by J-Code. For these reimbursements, I conclude the following:[29]

- For those drugs for which I have ASPs and AA > ASP = EAC, I conclude that AA fraudulently exceeds EAC. The ASPs will be delineated by J-Code. Given the time consuming process of performing the cross-walk for multi-source physician-administered drugs reimbursed by J-Code, I do not analyze liability for physician-administered drugs once they go generic. Note that this exclusion will make my calculation of penalties conservative.
- Evidence demonstrates that for single-source drugs, physician acquisition cost (PAC) is at most equal to WAC and often much less (i.e., PAC < AWP – (20%-75%).
- Absent a measure of ASP, and given the fact that I have not made a complete enough analysis of the pattern of increasing discounts off AWP over the Damage Period, I conclude that a reasonable threshold for liability for the Damage Period as a whole is AA > AWP – 25%. If AA exceeds this threshold, I conclude AA fraudulently exceeds EAC.
- However, I bound this threshold by allowing the threshold to be AWP – 20% and AWP – 66%.
- Again, because Medicare shifted in 2005 to reimbursement based upon ASP, I do not include any reimbursement claims for 2005, if they are present in the data.

III. Selected Issues Arising with Implementation of the Formulaic Methodology for Damage Calculation

A. Reimbursement for Drug Claims Under Montana's Medicaid Program

24. The reliance of Montana's Medicaid Program upon AWP for reimbursement resembles Medicaid reimbursement in most states.[30] The *Complaint* (¶162) states

> "The Montana Medicaid program *presently* reimburses for outpatient drugs on the basis of the lower of (i) estimated acquisition cost ("EAC") or the maximum allowable costs ("MAC" [which is calculated as FUL by Montana – the Federal Upper Limit]) plus a dispensing fee … or (ii) the provider's usual and customary charge [U&C]."[31]

25. However, the EAC is consistently less than U&C (the "walk-in" price charged to uninsured cash payers, which is usually ≈ AWP), MAC (= FUL) (which is 150%* the lowest AWP or WAC) and AWP – x% (10% or 15%). Thus, while legislation and

[29] I express these comparisons in terms of AA and EAC, understanding that the amounts recorded by the State are actually 20% thereof.

[30] See Attachment D generally and Table D-1 specifically of my September 3, 2004 Declaration in Support of Class Certification in this matter.

[31] See Transmittal and Notice of Approval of State Plan Material for Montana, Attachment 4.19B, Methods and Standards,TN 00-008, effective date October 1, 2000. Definition of MAC is discussed in footnote 10 above.

regulation of the Medicaid drug program has encouraged states to base their payments on Estimated Acquisition Cost (EAC = ASP), state Medicaid programs have not. Instead, they have been forced to base their reimbursements on AWP.[32] As a result, Defendant Manufacturers' AWP Scheme and reliance by the State upon AWP has caused the State of Montana to be overcharged as follows.

Using the notation of ¶¶ 15-16 above

a) For self-administered drugs "*presently*," $AA = AWP - 15\% + df = (100\% - 15\%)*AWP + df = 0.85*AWP + df$, and $AA^{but\text{-}for} = EAC + df = ASP + df$.

b) For self-administered drugs "*formerly*," $AA = AWP - 10\% + df = 0.90*AWP + df$, and $AA^{but\text{-}for} = EAC + df = ASP + df$.

c) I have been informed by Counsel that the reimbursement formula switched from AWP - 10% to AWP - 15% on July 1, 2002.[33]

d) For physician-administered drugs reimbursed by Montana as a drug claim (and therefore reported by NDC), I assume the same reimbursement formulae.

26. While Montana statutes indicate that the amount allowed on all, or at least substantially all, drug claims is formulaically based on AWP in this fashion, the actual calculation of AA_i, $\Sigma_i AA_i$ and AA^{avg} in Section IV below is based upon the claims themselves. Actual claim amounts are compared with actual ASPs, when those ASPs are available.

27. When ASPs have not been available and I have relied upon the thresholds determined as in ¶¶ 22-23 above, I also rely upon claims data and the thresholds calculated relative to AWPs.

B. Reimbursement for Drugs Reported as Medical Claims Under Montana's Medicaid Program

28. Medicaid reimburses for physician-administered drugs recorded as Medical claims using J-Codes for two groups of patients: i) those patients strictly covered by Medicaid, and ii) those patients covered by Medicare whose 20% co-insurance is covered by Medicaid ("dual eligibles"). Reimbursement formulae and calculation issues for the first set of medically-related drug claims are the same as those discussed above in ¶¶ 24-27 for Medicaid drug claims.

29. Reimbursement formulae and calculation issues for the second set of medically-related drug claims (dual eligibles) are determined by the Medicare reimbursement formulae presented in footnote 13 of my December 15, 2005 MDL Declaration on Liability and the Calculation of Damages. While these claims could be analyzed in a fashion similar to that put forward above, the Montana data for these claims do not disaggregate the 20% drug coinsurance payment from the 20% coinsurance payment for all medical services provided by the physician administering the physician-administered

[32] See ¶ 8 and footnote 9 above.

[33] I have examined the Montana Medicaid Drug Claims and confirmed that the switch in AA to AWP – 15% did occur on July 1, 2002.

drug. I did not have sufficient time to identify the allowed amount AA_i for the drug alone on these claims, in order to calculate overcharges and penalties. For this reason, I do not compare a claimed amount to the AWP of the drug (by J-Code), in order to identify the number of false claims. Likewise, I do not calculate damages or penalties for this group of claims. Hence, my calculation of aggregate overcharge damages and my measures of penalties for false and deceptive claims are conservative.

C. Reimbursement for Drug Claims and Medical Claims For State Employees and State Agencies

30. The drugs for which reimbursement was paid based upon AWP by these groups will likewise be categorized as self-administered branded drugs, self-administered generic drugs or physician-administered drugs. Calculation of overcharge damages and the penalties for false and deceptive claims would proceed as above, if I had been provided with claims data for these groups. I was not, and do not therefore calculate overcharge damages or identify the number of false and deceptive claims subject to recovery of penalties. Hence, my calculation of aggregate overcharge damages and my measures of penalties for false and deceptive claims are conservative.

D. Reimbursement for Drug Payments Made by Uninsured Consumers

31. The price of drugs to walk-in customers without insurance is understood to be U&C ≈ AWP. Such consumers have been overcharged by the AWP Scheme. I have no data summarizing these reimbursements; hence, I cannot calculate the related damages or penalties. Hence, my calculation of aggregate overcharge damages and my measures of penalties for false and deceptive claims are conservative.

E. Analysis of Medicaid Rebates

32. I have not received complete data on Medicaid rebates paid to the State. According to the CMS Medicaid Drug Rebate Program, Medicaid rebates are to be calculated as a fixed percentage of AMP ("Average Manufacturer Price"),[34] which purports to approximate the ASP. For the purposes of the overcharge damage analysis, I assume that AMP is the same in the actual and but-for worlds (since ASP is the same), and therefore the total amount of rebates received by the state is the same in the actual and but-for worlds. As a result, if properly paid in the actual world, Medicaid rebates net

[34] See http://www.cms.hhs.gov/MedicaidDrugRebateProgram; rebates for innovator drugs are set at 15.1% of AMP; and rebates for non-innovator drugs are set at 11% of AMP.

out of the damage calculation.[35] However, if rebates were not paid in the actual world, overcharge damages incurred by the State are higher than those calculated here.[36]

IV. The Calculation of Damages and Recovery of Penalties for False Claims and Deceptive Practices

33. Tables 1-6 summarize the calculations of overcharge damages and the measures of recovery for false claims and deceptive practices, making use of the methodologies presented above.[37]

a) Table 1 presents selected overcharge damages by Defendant and by Drug, when the reimbursement claims provided by Montana are drug claims based upon NDCs. Recall that almost no information was available to me to calculate aggregate overcharge damages. As a result, the sum of overcharge damages in Table 1 is useful for illustration rather than as a basis for recovery for economic injury.

b) Table 2 presents selected overcharge damages by Defendant and by Drug, when the reimbursement claims provided by Montana are medical claims that include reimbursement for drugs by J-Code and provision of physician services by CPT-Code. As with Table 1, almost no information was available to me to calculate aggregate overcharge damages by J-Code, and this sum of overcharge damages is useful for illustration only rather than as a basis for recovery for economic injury.

c) Table 3 summarizes my analysis of claims data for single-source self-administered drugs. It presents information regarding the total number of claims for such drugs by Defendant; it tabulates those claims that can be identified as false or deceptive by comparison of the claimed amount (AA) with drugs' ASPs and those identified on the basis of the threshold amounts related to the drugs' AWP. I have allowed for two thresholds: AA > AWP – 16.6% and AA > AWP –

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[35] State reimbursements for Medicaid should net out rebate payments. Specifically, Actual Net Reimbursements = Actual Reimbursements – Actual Rebates. Likewise, But-For Net Reimbursements = But-For Reimbursements – But-For Rebates. Therefore, Overcharge Damages = Actual Net Reimbursements – But-For Reimbursements = (Actual Reimbursements – Actual Rebates) – (But-For Reimbursements – But-For Rebates). However, since ASP and AMP are the same in both the but-for and actual worlds, Actual Rebates = But-For Rebates, and Overcharge Damages = Actual Reimbursements – But-For Reimbursements (as in Equation (1c)).

[36] Using the notation in the preceding footnote, Overcharge Damages = Actual Net Reimbursements – But-For Reimbursements = (Actual Reimbursements – Actual Rebates) – (But-For Reimbursements – But-For Rebates). When rebates are paid in the actual world and by reasonable assumption are the same in the but-for world, the rebates net out of the damage calculation, as above. If however, Actual Rebates = $0 when Actual Rebates should = But-For Rebates > 0, then Corrected Overcharge Damages = (Actual Reimbursements – 0.00) – (But-For Reimbursements – But-For Rebates) = (Actual Reimbursements – But-For Reimbursements) + **But-For Rebates** > my calculated Overcharge Damages = Actual Reimbursements – But-For Reimbursements.

[37] Note that none of these calculations take account of pre-judgment interest. They are therefore conservative.

20%. If AA exceeds the ASP or the threshold, I conclude AA fraudulently exceeds EAC.

d) Table 4 summarizes my analysis of claims data for multi-source self-administered drugs. It presents information regarding the total number of claims for such drugs by Defendant; it tabulates those claims that can be identified as false or deceptive by comparison of the claimed amount (AA) with drugs' ASPs and those identified on the basis of the threshold amounts related to the drugs' AWP. While I conclude that the threshold of AWP – 25% is reasonable for the Damage Period as a whole, I bound this threshold by allowing the liability threshold to be AWP – 20% and AWP – 66%.

e) Table 5 summarizes my analysis of claims data for physician-administered drugs reimbursed under Medicaid, excluding claims for "dual eligibles." It presents information regarding the total number of claims for such drugs by Defendant and those that can be identified as false or deceptive by comparison of the claimed amount (AA) with drugs' ASP and those identified on the basis of the threshold amounts related to the drugs' AWP. While I conclude that the threshold of AWP – 25% is conservative for the Damage Period as a whole, I bound this threshold by allowing the liability threshold to be AWP – 20% and AWP – 66%.

34. To summarize the results of these Tables, I find (and report where appropriate in Table 6)

a) Given the paucity of data I can effectively use to calculate actual ASPs, I am able to calculate overcharge damages for a *de minimis* number of drugs designated by NDC or J-Code. The measure of aggregate overcharge damages for both sets of drugs found in Tables 1 and 2 is $1.45 million (see Table 6, column 1).

b) The number of claims that are false and subject to deceptive practices is substantial under widely different bounds for reasonable thresholds of calculating the EAC relative to the reported AWP.

- In Table 3, the total number of such claims for single-source self-administered drugs ranges from a low of 6 (for Watson) to a high of 538,359 (for Pfizer) across Defendants. Since the penalty for such deceptive and false practices is $3,000 in total, the amount of the recovery for that penalty is also substantial, ranging from $18,000 (Watson) to $1.6 billion (Pfizer) across Defendants. The total recovery for this class of drugs for this Period ranges from $4.4 billion to $5.9 billion, depending upon the threshold.
- In Table 4, the total number of such claims for multi-source self-administered drugs ranges from 2 (for the Aventis Group) to 96,354 (for Schering-Plough[38]) across Defendants. Again, since the penalty for such deceptive and false practices is $3000 in total, the amount of the recovery for that penalty is also substantial, ranging from $6,000 (for Aventis Group) to $289 million (for

[38] Note that this total includes those based upon comparing the AA with the ASP (86,471) and those based upon comparing the AA with the 66%*AWP threshold (9,883). Dey has the largest number of claims based upon the threshold comparison alone (41,789).

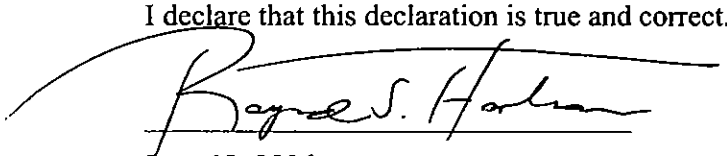
Schering-Plough) across Defendants. The total recovery for this class of drugs for this Period ranges from $395 million to $583 million, depending upon the threshold.

- In Table 5, the total number of such claims for physician-administered drugs ranges from 1 (for Novartis) to 2,408 (for Amgen) across Defendants. The amount of the recovery for that penalty ranges from $3,000 (for Novartis) to $7.2 million (for Amgen) across Defendants. The total recovery for this class of drugs for this Period ranges from $11.5 million to $15.4 million, depending on the threshold.
- In Table 6, the range of penalties based upon the bounds for the yardstick thresholds is $4.77 billion to $6.47 billion (summed over Table 3-5).

35. While the assumptions regarding thresholds for EAC in Tables 3-5 are reasonable, they are assumptions. In Table 7, I present supplemental calculations for the number of false and deceptive claims making no assumption regarding EAC. Instead, I count the number of claims for each type of drug (single-source self-administered, multi-source self-administered and physician-administered) the allowed amount for which exceeds that amount allowed under the Montana Medicaid statute; i.e., AA > AWP – 10% and AA > AWP – 15% for the relevant periods of time (see ¶¶ 24-25 above). Note that I conduct this analysis only for the claims for which I do not have ASPs and therefore have made assumptions about the thresholds for EAC. For those drugs for which I have ASPs, I can relate AA to the EAC = ASP.

For those drugs for which I can calculate ASPs, Table 7 indicates that the allowed amount exceeds the ASP on 16,518 claims for single-source drugs and 87,312 claims for multi-source drugs. Using the statutory reimbursement amounts for those drugs for which I do not have ASPs, I find that the amount allowed exceeds the statutory reimbursement allowance on 388,628 claims for single-source drugs and on 16,270 claims for multi-source drugs. For all claims identified as false and deceptive in Table 7, I find that total penalties are $1.5 billion across Defendants.

I declare that this declaration is true and correct.



June 13, 2006

Attachment A

Additional Materials Relied Upon

Hartman, Raymond, Declaration of Raymond S. Hartman, *State of Connecticut v. Dey, Inc., et al.*, January 19, 2006 and Expert Disclosure, Raymond S. Hartman, *State of Connecticut v. Dey, Inc., et al.*, November 1, 2005

State of Montana, State of Montana's Second Amended Complaint, *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, , MDL No. 1456, United States District Court for the District of Massachusetts, August 1, 2003

U.S. Department of Health and Human Services, OIG, *Medicaid Pharmacy - Actual Acquisition Cost of Generic Prescription Drug Products*, A-06-01-00053, March 2002

Table 1: Calculation of Overcharge Damages for Selected Drugs Reimbursed Based on NDCs

Defendant	Drug	Total by Drug
AstraZeneca	Pulmicort Respules	38,277
AstraZeneca	Zoladex	54,371
AstraZeneca Total		**$92,648**
Aventis	Anzemet	3,655
Aventis	Taxotere	802
Aventis Group Total		**$4,457**
BMS	Blenoxane	796
BMS	Cytoxan	5,281
BMS	Paraplatin	181
BMS	Taxol	412
BMS	Vepesid	5,580
BMS Group Total		**$12,250**
Johnson & Johnson	Procrit	49,464
Johnson & Johnson	Remicade	16,384
Johnson & Johnson Total		**$65,848**
Pharmacia	Adriamycin	5,249
Pharmacia	Amphocin	311
Pharmacia Group Total		**$5,561**
Schering-Plough	Albuterol	782,046
Schering-Plough	Intron	14,381
Schering-Plough	Proventil	21,729
Schering-Plough	Temodar	18,760
Warrick Pharmaceuticals	Perphenazine	11,003
Schering-Plough Group Total		**$847,939**
Total Overcharges for Selected Drugs		**$1,028,703**

Table 2: Calculation of Overcharge Damages for Selected Drugs Reimbursed Based on J-Codes

Manufacturer	Drug	J-Code	Total by Drug
AstraZeneca	ZOLADEX	J9202	$14,066
Aventis	TAXOTERE	J9170	$246,437
BMS Group	TAXOL	J9265	$50,850
Johnson & Johnson Group	REMICADE	J1745	$8,926
Johnson & Johnson Group	PROCRIT	Q0136	$23,350
Pharmacia	ANZEMET	J1260	$81,563
Total Overcharges for Selected Drugs by J-Code			$425,196

Table 3: Deceptive Trade and False Claims Penalties - Single-Source Drugs

		Analysis Using ASP		*Analysis Using AWP Thresholds* [1]			*Penalties (ASP and (AWP - 16.6%))*			*Penalties (ASP and (AWP - 20.0%))*		
	Total # of Claims	# of Claims Used in ASP Analysis	# of Fraudulent Claims	# of Claims Used in AWP Threshold Analysis	# of Fraudulent Claims Based on (AWP-16.6%)	# of Fraudulent Claims Based on (AWP-20.0%)	Deceptive Trade ($1000/claim)	False Claim ($2000/claim)	Total Penalties	Deceptive Trade ($1000/claim)	False Claim ($2000/claim)	Total Penalties
Abbott	44,153	0	0	44,153	12,952	14,530	$12,952,000	$25,904,000	$38,856,000	$14,530,000	$29,060,000	$43,590,000
Amgen	4,424	0	0	4,424	3,896	4,262	$3,896,000	$7,792,000	$11,688,000	$4,262,000	$8,524,000	$12,786,000
AstraZeneca	224,548	5,280	5,081	219,268	125,166	189,713	$130,247,000	$260,494,000	$390,741,000	$194,794,000	$389,588,000	$584,382,000
Aventis Group	131,573	39	35	131,534	94,013	117,323	$94,048,000	$188,096,000	$282,144,000	$117,358,000	$234,716,000	$352,074,000
Baxter	292	0	0	292	125	127	$125,000	$250,000	$375,000	$127,000	$254,000	$381,000
Bayer	47,582	0	0	47,582	40,336	44,663	$40,336,000	$80,672,000	$121,008,000	$44,663,000	$89,326,000	$133,989,000
Boehringer Group	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Braun	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
BMS Group	330,533	645	626	329,888	234,287	283,598	$234,913,000	$469,826,000	$704,739,000	$284,224,000	$568,448,000	$852,672,000
Dey	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Fujisawa Group	1,483	0	0	1,483	963	1,246	$963,000	$1,926,000	$2,889,000	$1,246,000	$2,492,000	$3,738,000
Immunex	30	0	0	30	30	30	$30,000	$60,000	$90,000	$30,000	$60,000	$90,000
Johnson & Johnson	348,519	196	195	348,323	247,561	310,495	$247,756,000	$495,512,000	$743,268,000	$310,690,000	$621,380,000	$932,070,000
Novartis	247,494	0	0	247,494	176,750	220,231	$176,750,000	$353,500,000	$530,250,000	$220,231,000	$440,462,000	$660,693,000
Pfizer	654,287	0	0	654,287	334,584	538,359	$334,584,000	$669,168,000	$1,003,752,000	$538,359,000	$1,076,718,000	$1,615,077,000
Pharmacia Group	40,110	12	12	40,098	22,845	33,410	$22,857,000	$45,714,000	$68,571,000	$33,422,000	$66,844,000	$100,266,000
Schering-Plough Group	141,993	9,920	9,609	132,073	90,149	110,295	$99,756,000	$199,516,000	$299,274,000	$119,904,000	$239,808,000	$359,712,000
Sicor Group	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
TAP	78,278	0	0	78,278	54,341	74,039	$54,341,000	$108,682,000	$163,023,000	$74,039,000	$148,078,000	$222,117,000
Watson	6	0	0	6	6	6	$6,000	$12,000	$18,000	$6,000	$12,000	$18,000
Total-All Defendants	2,295,305	16,092	15,558	2,279,213	1,438,004	1,942,327	$1,453,562,000	$2,907,124,000	$4,360,686,000	$1,957,885,000	$3,915,770,000	$5,873,655,000

Notes:
1. Total Number of claims used in the AWP threshold analysis will not equal the sum of fraudulent claims found using the different AWP thresholds.

Table 4: Deceptive Trade and False Claims Penalties - Multi-Source Drugs

		Analysis Using ASP		*Analysis Using AWP Thresholds* [1]			*Penalties (ASP and (AWP - 20.0%))*			*Penalties (ASP and (AWP - 65.9%))*		
	Total # of Claims	# of Claims Used in ASP Analysis	# of Fraudulent Claims	# of Claims Used in AWP Threshold Analysis	# of Fraudulent Claims Based on (AWP-20.0%)	# of Fraudulent Claims Based on (AWP-66.0%)	Deceptive Trade ($1000/claim)	False Claim ($2000/claim)	Total Penalties	Deceptive Trade ($1000/claim)	False Claim ($2000/claim)	Total Penalties
Abbott	15,449	0	0	15,449	7,705	14,020	$7,705,000	$15,410,000	$23,115,000	$14,020,000	$28,040,000	$42,060,000
Amgen	191	0	0	191	178	185	$178,000	$356,000	$534,000	$185,000	$370,000	$555,000
AstraZeneca	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Aventis Group	2	0	0	2	2	2	$2,000	$4,000	$6,000	$2,000	$4,000	$6,000
Baxter	5,352	0	0	5,352	2,391	3,906	$2,391,000	$4,782,000	$7,173,000	$3,906,000	$7,812,000	$11,718,000
Bayer	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Boehringer Group	15	0	0	15	7	9	$7,000	$14,000	$21,000	$9,000	$18,000	$27,000
Braun	3,320	0	0	3,320	1,950	2,576	$1,950,000	$3,900,000	$5,850,000	$2,576,000	$5,152,000	$7,728,000
BMS Group	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Dey	51,373	0	0	51,373	22,244	41,789	$22,244,000	$44,488,000	$66,732,000	$41,789,000	$83,578,000	$125,367,000
Fujisawa Group	5	0	0	5	5	5	$5,000	$10,000	$15,000	$5,000	$10,000	$15,000
Immunex	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Johnson & Johnson	3,494	881	836	2,613	2,414	2,605	$3,250,000	$6,500,000	$9,750,000	$3,441,000	$6,882,000	$10,323,000
Novartis	1,339	0	0	1,339	1,241	1,337	$1,241,000	$2,482,000	$3,723,000	$1,337,000	$2,674,000	$4,011,000
Pfizer	1,661	0	0	1,661	350	1,448	$350,000	$700,000	$1,050,000	$1,448,000	$2,896,000	$4,344,000
Pharmacia Group	32	8	5	24	17	22	$22,000	$44,000	$66,000	$27,000	$54,000	$81,000
Schering-Plough Group	99,192	86,966	86,471	12,226	4,598	9,883	$91,069,000	$182,138,000	$273,207,000	$96,354,000	$192,708,000	$289,062,000
Sicor Group	5	0	0	5	5	5	$5,000	$10,000	$15,000	$5,000	$10,000	$15,000
TAP	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Watson	41,303	0	0	41,303	1,280	29,235	$1,280,000	$2,560,000	$3,840,000	$29,235,000	$58,470,000	$87,705,000
Total-All Defendants	222,733	87,855	87,312	134,878	44,367	107,027	$131,699,000	$263,398,000	$395,097,000	$194,339,000	$388,678,000	$583,017,000

Notes:
1. Total Number of claims used in the AWP threshold analysis will not equal the sum of fraudulent claims found using the different AWP thresholds.

Table 5: Deceptive Trade and False Claims Penalties - Physician Administered Drugs

		Analysis Using ASP		*Analysis Using AWP Thresholds*[1]			*Penalties (ASP and (AWP - 20.0%))*			*Penalties (ASP and (AWP - 65.9%))*		
	Total # of Claims	# of Claims Used in ASP Analysis	# of Fraudulent Claims	# of Claims Used in AWP Threshold Analysis	# of Fraudulent Claims Based on (AWP-20.0%)	# of Fraudulent Claims Based on (AWP-66.0%)	Deceptive Trade ($1000/claim)	False Claim ($2000/claim)	Total Penalties	Deceptive Trade ($1000/claim)	False Claim ($2000/claim)	Total Penalties
Abbott	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Amgen	2,422	0	0	2,422	1,616	2,408	$1,616,000	$3,232,000	$4,848,000	$2,408,000	$4,816,000	$7,224,000
AstraZeneca	80	36	36	44	43	43	$79,000	$158,000	$237,000	$79,000	$158,000	$237,000
Aventis Group	440	122	122	318	318	318	$440,000	$880,000	$1,320,000	$440,000	$880,000	$1,320,000
Baxter	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Bayer	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Boehringer Group	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Braun	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
BMS Group	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Dey	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Fujisawa Group	47	0	0	47	47	47	$47,000	$94,000	$141,000	$47,000	$94,000	$141,000
Immunex	16	0	0	16	16	16	$16,000	$32,000	$48,000	$16,000	$32,000	$48,000
Johnson & Johnson	960	802	802	158	158	158	$960,000	$1,920,000	$2,880,000	$960,000	$1,920,000	$2,880,000
Novartis	2	0	0	2	1	2	$1,000	$2,000	$3,000	$2,000	$4,000	$6,000
Pfizer	14	0	0	14	14	14	$14,000	$28,000	$42,000	$14,000	$28,000	$42,000
Pharmacia Group	39	0	0	39	39	39	$39,000	$78,000	$117,000	$39,000	$78,000	$117,000
Schering-Plough Group	1,078	0	0	1,078	580	1,078	$580,000	$1,160,000	$1,740,000	$1,078,000	$2,156,000	$3,234,000
Sicor Group	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
TAP	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Watson	52	0	0	52	52	52	$52,000	$104,000	$156,000	$52,000	$104,000	$156,000
Total-All Defendants	5,150	960	960	4,190	2,864	4,175	$3,844,000	$7,688,000	$11,532,000	$5,135,000	$10,270,000	$15,405,000

Notes:
1. Total Number of claims used in the AWP threshold analysis will not equal the sum of fraudulent claims found using the different AWP thresholds.

Table 6: Summary of Overcharge Damages and Penalties by Defendant and Total

		Penalties - Based on Yardstick Threshold Bounds[2]	
	All Overcharges[1]	Lower Bound	Upper Bound
Abbott	$0	$61,971,000	$85,650,000
Amgen	$0	$17,070,000	$20,565,000
AstraZeneca	$106,714	$390,976,000	$584,619,000
Aventis Group	$250,895	$263,470,000	$353,400,000
Baxter	$0	$7,548,000	$12,099,000
Bayer	$0	$121,008,000	$133,989,000
Boehringer Group	$0	$21,000	$27,000
Braun	$0	$5,850,000	$7,728,000
BMS Group	$63,100	$704,739,000	$852,672,000
Dey	$0	$68,732,000	$125,367,000
Fujisawa Group	$0	$3,045,000	$3,894,000
Immunex	$0	$138,000	$138,000
Johnson & Johnson	$98,126	$755,898,000	$945,273,000
Novartis	$0	$533,976,000	$664,710,000
Pfizer	$0	$1,004,844,000	$1,619,463,000
Pharmacia Group	$87,124	$68,754,000	$100,464,000
Schering-Plough Group	$847,939	$574,221,000	$652,008,000
Sicor Group	$0	$15,000	$15,000
TAP	$0	$163,023,000	$222,117,000
Watson	$0	$4,014,000	$87,879,000
Total-All Defendants	$1,453,898	$4,767,315,000	$6,472,077,000

Notes:
1. Tables 1 and 2.
2. Tables 3, 4 and 5.

Table 7: Deceptive Trade and False Claims Penalties - Innovator and Multi-Source Drugs (Statute Change)

		Analysis Using ASP			*Analysis Using AWP Statute*			*Innovator Penalties (ASP and Statute Change in July 2002 from AWP - 10% to AWP - 15%)*			*Multi-Source Penalties (ASP and Statute Change in July 2002 from AWP - 10% to AWP - 15%)*			*Total Statute Penalties*
	Total # of Claims	# of Claims Used in ASP Analysis[1]	# of Fraudulent Claims (Innovator)[2]	# of Fraudulent Claims (Multi-Source)[3]	# of Claims Used in AWP Statute Analysis[4]	# of Innovator Fraudulent Claims Based on Statute (10%-15%)[5]	# of Multi-Source Fraudulent Claims Based on Statute (10%-15%)[6]	Deceptive Trade ($1000/claim)	False Claim ($2000/claim)	Total Penalties	Deceptive Trade ($1000/claim)	False Claim ($2000/claim)	Total Penalties	Total Penalties
Abbott	59,602	0	0	0	59,602	1,327	1,500	$1,327,000	$2,654,000	$3,981,000	$1,500,000	$3,000,000	$4,500,000	$8,481,000
Amgen	7,037	0	0	0	7,037	1,129	35	$1,129,000	$2,258,000	$3,387,000	$35,000	$70,000	$105,000	$3,492,000
AstraZeneca	224,628	5,316	5,117	0	219,312	25,284	0	$30,401,000	$60,802,000	$91,203,000	$0	$0	$0	$91,203,000
Aventis Group	132,015	161	157	0	131,854	29,368	0	$29,525,000	$59,050,000	$88,575,000	$0	$0	$0	$88,575,000
Baxter	5,644	0	0	0	5,644	54	1,134	$54,000	$108,000	$162,000	$1,134,000	$2,268,000	$3,402,000	$3,564,000
Bayer	47,582	0	0	0	47,582	10,685	0	$10,685,000	$21,370,000	$32,055,000	$0	$0	$0	$32,055,000
Boehringer Group	15	0	0	0	15	0	1	$0	$0	$0	$1,000	$2,000	$3,000	$3,000
Braun	3,320	0	0	0	3,320	0	852	$0	$0	$0	$852,000	$1,704,000	$2,556,000	$2,556,000
BMS Group	330,533	645	626	0	329,888	69,762	0	$70,388,000	$140,776,000	$211,164,000	$0	$0	$0	$211,164,000
Dey	51,373	0	0	0	51,373	0	8,892	$0	$0	$0	$8,892,000	$17,784,000	$26,676,000	$26,676,000
Fujisawa Group	1,535	0	0	0	1,535	285	3	$285,000	$570,000	$855,000	$3,000	$6,000	$9,000	$864,000
Immunex	46	0	0	0	46	16	0	$16,000	$32,000	$48,000	$0	$0	$0	$48,000
Johnson & Johnson	352,973	1,879	997	836	351,094	66,134	667	$67,131,000	$134,262,000	$201,393,000	$1,503,000	$3,006,000	$4,509,000	$205,902,000
Novartis	248,835	0	0	0	248,835	59,344	284	$59,344,000	$118,688,000	$178,032,000	$284,000	$568,000	$852,000	$178,884,000
Pfizer	655,962	0	0	0	655,962	88,598	81	$88,598,000	$177,196,000	$265,794,000	$81,000	$162,000	$243,000	$266,037,000
Pharmacia Group	40,161	20	12	5	40,161	5,912	6	$5,924,000	$11,848,000	$17,772,000	$11,000	$22,000	$33,000	$17,805,000
Schering-Plough Group	242,263	96,886	9,609	86,471	145,377	18,061	2,533	$27,670,000	$55,340,000	$83,010,000	$89,004,000	$178,008,000	$267,012,000	$350,022,000
Sicor Group	5	0	0	0	5	0	0	$0	$0	$0	$0	$0	$0	$0
TAP	78,278	0	0	0	78,278	12,669	0	$12,669,000	$25,338,000	$38,007,000	$0	$0	$0	$38,007,000
Watson	41,361	0	0	0	41,361	0	292	$0	$0	$0	$292,000	$584,000	$876,000	$876,000
Total-All Defendants	2,523,188	104,907	16,518	87,312	2,418,281	388,628	16,280	$405,146,000	$810,292,000	$1,215,438,000	$103,592,000	$207,184,000	$310,776,000	$1,526,214,000

Notes:
1. Tables 3, 4 and 5.
2. Tables 3 and 5.
3. Table 4.
4. Tables 3, 4 and 5.
5. Table 3. These Totals also include the number of fraudulent claims calculated from the Medical claims data, based on the same statutory thresholds.
6. Table 4.

Exhibit 50

EXHIBIT 16 2/22/06 Pontsler

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: HEALTH CARE FINANCING ADMINISTRATION

1. TRANSMITTAL NUMBER: 00-03

2. STATE: MONTANA

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)

TO: REGIONAL ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE
10/1/2000

5. TYPE OF PLAN MATERIAL *(Check One)*:

☐ NEW STATE PLAN ☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN ☒ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *(Separate Transmittal for each amendment)*

6. FEDERAL STATUTE/REGULATION CITATION:
42 CFR 447. 325-334

7. FEDERAL BUDGET IMPACT:
a. FFY $ 0
b. FFY $ 0

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:
Attachment 4.19B Service 12a
Outpatient Drug Services

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:
Attachment 4.19B Service 12a
Outpatient Drug Services

10. SUBJECT OF AMENDMENT:
Outpatient Drug Services

11. GOVERNOR'S REVIEW *(Check One)*:

☐ GOVERNOR'S OFFICE REPORTED NO COMMENT
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
☒ OTHER, AS SPECIFIED:
Single State Agency Director

12. SIGNATURE OF STATE AGENCY OFFICIAL:
Laurie Ekanger

13. TYPED NAME:
Laurie, Ekanger

14. TITLE:
Director

15. DATE SUBMITTED:

16. RETURN TO:
Department of Public Health & Human Services
Laurie Ekanger, Director
Attn: Jean Robersson
PO Box 202951
Helena, MT 59620-2

FOR THE HCFA CENTRAL OFFICE ONLY

17. DATE RECEIVED
10/2/00

18. DATE APPROVED

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL
10-1-00

20. SIGNATURE OF REGIONAL OFFICIAL

21. TYPED NAME:
Dave Selleck

22. TITLE:

23. REMARKS

FORM HCFA-179 (07-92)

Instructions on Back

EXHIBIT Bush023 CRR 12-19-05

MONTANA

Reimbursement for drugs shall not exceed the lowest of:

1. The Estimated Acquisition Cost (EAC) of the drug plus a dispensing fee, or;
2. The Federal Upper Limit (FUL), Maximum Allowable Cost (MAC) of the drug, in the case of mutli-source (generic), plus a dispensing fee, or;
3. The provider's usual and customary charge of the drug to the general public.

Exception: The FUL or MAC limitation shall not apply in a case where a physician certifies in his/her own handwriting the specific brand is medically necessary for a particular recipient. An example of an acceptable certification is the handwritten notation "Brand Necessary" or "Brand Required." A check off box on a form or rubber stamp is not acceptable.

Exception: For outpatient drugs provided to medicaid recipients in state institutions, reimbursement will conform to the state contract for pharmacy services; or for institutions not participating in the state contract for pharmacy services, reimbursement will be the actual cost of the drug and dispensing fee. In either case, reimbursement will not exceed, in the aggregate, the EAC or the MAC plus the dispensing fee.

The EAC is established by the state agency using the Federal definition of EAC as a guideline: that is, "Estimated Acquisition Cost" means the state agency's best estimate of what price providers generally pay for a particular drug.

The EAC, which includes single source, brand necessary and drugs other than multi-source, is established using the following methodology:

- The Direct Price (DP), the price charged by manufacturers to retailers, will be paid unless the DP is not available to providers in the state. If no DP is available, drugs paid by their Average Wholesale Price (AWP) will be paid at AWP less 10%. If the state agency determines that acquisition cost is lower than either the available DP or AWP less 10%, then the state agency may set an allowable acquisition cost based on data provided by the drug pricing file contractor.

The MAC for multiple source drugs will not exceed the total of the dispensing fee established by the Department and an amount that is equal to 150 percent of the price established under the methodology set forth in 42 CFR 447.331 and 447.332 for the least costly therapeutic equivalent.

A variable dispensing fee will be established by the state agency, by using the results of a cost survey of pharmacy's operational costs. A pharmacy may be assigned an enhanced dispensing fee to cover the additional costs associated with packaging "unit dose" prescriptions.

Provider dispensing fee(s) are available on-line in the Medicaid Management Information system (MMIS) provider file and in the Medicaid Prescription Drug Card System (PDCS) provider plan file.

Exhibit 51

EXHIBIT 5 2/22/06 Poulsen

TESTIMONY
Outpatient Drugs
January 6, 1998

I am Dorothy Poulsen, pharmacy program officer for the Medicaid Services Bureau of the Department of Public Health and Human Services. I will briefly describe the proposed rules and explain the Department's reasons for proposing the adoption of Rule I and amendments to ARM 46.12.102, 46.12.702 and 46.12.703 pertaining to Medicaid coverage and reimbursement for outpatient drugs.

The primary purpose of the proposed changes to the outpatient drug rules is to implement the 1.5% provider increase passed in the 1997 Montana General Appropriations Act. We have also taken this opportunity to revise portions of the rules that are no longer applicable, have caused confusion, or have outdated legal references, dates, etc.

RULE I: We have transferred definitions from ARM 46.12.102(19), (2), and (21) to Rule I because these definitions are currently in sub-chapter 1 which pertains to general requirements of the Medicaid program. Since these definitions apply specifically to outpatient drugs, they are more appropriately located within sub-chapter 7, Outpatient Drugs. A definition for "legend drugs" was added because of other revisions made in these rules. The definition of maximum allowable cost was changed because the current language is incorrect, and, if used, would overprice MAC drugs.

ARM 46.12.702 Outpatient Drugs, Requirements: The language in ARM 46.12.702(3) was changed to eliminate potential confusion about the phrase "drugs which require a prescription." Since Medicaid always requires a prescription for reimbursement, the intent of the phrase was unclear to some readers. Since this phrase was intended to refer to legend drugs, we have replaced the phrase with "legend drugs."

Revisions to ARM 46.12.702(5) eliminate references to acute and chronic conditions. These terms are ambiguous and have resulted in disputes with pharmacy providers. The intent of this rule is to specify the dispensing limits for the program when the prescriber does not order a specific quantity. The upper limits are easily defined but the minimum limits are more difficult to designate. The department's intention is that drugs be dispensed in as great a quantity, up to the limits, as is reasonable for the situation. For example, many nursing home patients use the same drugs for months or years. To dispense such drugs in less than monthly quantities is an abuse of the reimbursement methodology because frequently the major expense to the program in these cases is the dispensing fee rather than the drug product. To specify a minimum, however, would likely result in waste. To solve this dilemma, the department has left the current language "in sufficient quantities to cover the period of time for which the condition is being treated" as its minimum limit. Other changes in this rule "clean up" legal references, addresses, etc.

ARM 46.12.703 Outpatient Drugs, Reimbursement: Part (2) of the current rule contained several provisions that have been subdivided into proposed rules (2)(a), (b), (c), and (d). In (2)(a) the description of the basis for the dispensing fee has been simplified and updated and because it is obsolete, the description of the incentive factor was deleted. Part (2)(b) changes the cap for the dispensing fee to $4.14 to reflect the provider increase passed by the legislature. The other major revision of this rule is the addition of (5) describing the reimbursement for outpatient drugs provided to medicaid recipients in state institutions under the state contract.

BEFORE THE DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES OF THE STATE OF MONTANA

In the matter of the adoption of rule I and the amendment of 46.12.102, 46.12.702 and 46.12.703 pertaining to medicaid outpatient drugs	)))))	NOTICE OF PUBLIC HEARING OF PROPOSED ADOPTION AND AMENDMENT

TO: All Interested Persons

1. On January 6, 1998, at 9:30 a.m., a public hearing will be held in the auditorium of the Department of Public Health and Human Services Building, 111 N. Sanders, Helena, Montana to consider the proposed adoption of rule I and the amendment of 46.12.102, 46.12.702 and 46.12.703 pertaining to medicaid outpatient drugs.

The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who wish to participate in this public hearing or need an alternative accessible format of this notice. If you request an accommodation, contact the department no later than 5:00 p.m. on December 29, 1997, to advise us of the nature of the accommodation that you need. Please contact Dawn Sliva, Office of Legal Affairs, Department of Public Health and Human Services, P.O. Box 4210, Helena, MT 59604-4210; telephone (406)444-5622; FAX (406)444-1970.

2. The rule as proposed to be adopted provides as follows:

RULE I OUTPATIENT DRUGS, DEFINITIONS (1) "Outpatient drugs" means drugs which are obtained outside of a hospital.

(2) "Legend drugs" means drugs that federal law prohibits dispensing without a prescription.

(3) "Maximum allowable cost (MAC)" means the upper limit the department will pay for multi-source drugs. In order to establish base prices for calculating the maximum allowable cost, the department hereby adopts and incorporates by reference the methodology for limits of payment set forth in 42 CFR 447.331 and 447.332 (1996). The maximum allowable cost for multi-source drugs will not exceed the total of the dispensing fee established by the department and an amount that is equal to the price established under the methodology set forth in 42 CFR 447.331 and 447.332 for the least costly therapeutic equivalent that can be purchased by pharmacists in quantities of 100 tablets or capsules or, in the case of liquids, the commonly listed size. If the drug is not commonly available in quantities of 100, the package size commonly listed will be the accepted quantity. A copy of the above-cited regulations may be

obtained from the Department of Public Health and Human Services, Health Policy and Services Division, 1400 Broadway, P.O. Box 202951, Helena, Montana, 59620-2951.

(4) "Estimated acquisition cost (EAC)" means the cost of drugs for which no MAC price has been determined. The EAC is the department's best estimate of what price providers are generally paying in the state for a drug in the package size providers buy most frequently. The EAC for a drug is the direct price (DP) charged by manufacturers to retailers. If there is no available DP for a drug or the department determines that the DP is not available to providers in the state, the EAC is the average wholesale price (AWP) less 10%.

AUTH: Sec. 53-2-201 and 53-6-113, MCA
IMP: Sec. 53-2-201, 53-6-101, 53-6-111 and 53-6-113, MCA

3. The rules as proposed to be amended provide as follows. Material to be added is underlined. Material to be deleted is interlined.

46.12.102 MEDICAL ASSISTANCE, DEFINITIONS (1) through (18) remain the same.

~~(19) Outpatient drugs means drugs which are obtained outside of a hospital.~~

~~(20) Maximum allowable cost (MAC) is the upper limit the department will pay for multi source drugs. In order to establish base prices for calculating the maximum allowable cost, the department hereby adopts and incorporates by reference the methodology for limits of payment set forth in 42 CFR 447.331 and 447.332 (1988). The maximum allowable cost for multiple source drugs will not exceed the total of the dispensing fee established by the department and an amount that is equal to 150% of the price established under the methodology set forth in 42 CFR 447.331 and 447.332 for the least costly therapeutic equivalent that can be purchased by pharmacists in quantities of 100 tablets or capsules or, in the case of liquids, the commonly listed size. If the drug is not commonly available in quantities of 100, the package size commonly listed will be the accepted quantity. A copy of the above cited regulations may be obtained from the Department of Public Health and Human Services, Health Policy and Services Division, 1400 Broadway, P.O. Box 202951, Helena, Montana, 59620-2951.~~

~~(21) Estimated acquisition cost (EAC) is the cost of drugs for which no MAC price has been determined. The EAC is the department's best estimate of what price providers are generally paying in the state for a drug in the package size providers buy most frequently. The EAC for a drug is the direct price (DP) charged by manufacturers to retailers. If there is no available DP for a drug or the department determines that the DP is not available to providers in the state, effective January 1, 1988, the EAC is the average wholesale price (AWP) less 10%.~~

~~The department uses the DP and AWP as weekly reported or calculated by the American druggist blue book data center or any other industry accepted data center under contract with the department or its fiscal agent.~~

(22) through (37) remain the same in text, but are renumbered (19) through (34).

AUTH: Sec. 53-2-201 and 53-6-113, MCA
IMP: Sec. 53-2-201, 53-6-101, 53-6-106, 53-6-107, 53-6-111, 53-6-113, 53-6-131 and 53-6-141, MCA

46.12.702 OUTPATIENT DRUGS, REQUIREMENTS (1) and (2) remain the same.

(3) ~~The department will participate only in the payment of drugs which require a prescription and those over the counter drugs which are included in the department drug formulary. Over the counter drugs include, but are not limited to insulin, antacids or laxatives.~~ The department will participate only in the payment of legend drugs and those over the counter drugs which are included in the department drug formulary.

(4) remains the same.

(5) Each prescription shall be dispensed in the quantity ordered ~~by the physician~~ except that:

~~(a) Prescriptions for chronic conditions for which a physician has not ordered a specific quantity shall be dispensed in quantities of 100 dosages or a minimum of one month's supply of medication.~~

~~(b)~~(a) Prescriptions ~~for acute conditions~~ for which a ~~physician~~ specific quantity has not been ordered ~~a specific quantity~~ shall be dispensed in sufficient quantities to cover the period of time for which the condition is being treated except for injectable antibiotics, which may be dispensed in sufficient quantities to cover a three day period.

~~(c)~~(b) Notwithstanding the above, prescriptions ~~for all conditions~~ may not be dispensed in quantities greater than 100 dosages or a 34-day supply, whichever is greater.

(6) The department will not participate in the payment of prescription drugs:

(6)(a) remains the same.

(b) ~~effective April 1, 1991,~~ of a manufacturer with which the secretary of HHS has not signed a drug rebate agreement as required by ~~section 4401 of the Omnibus Budget Reconciliation Act of 1990, Public Law 101 508~~ 42 USC 1396r-8 (1997).

(c) subject to prior authorization as determined by the medicaid drug formulary committee, established and operating in accordance with ~~the Federal Omnibus Budget Reconciliation Act of 1993~~ 42 USC 1396r-8 (1997), without the existence of a prior authorization request approved by the department or its designated representative. A copy of drugs subject to prior authorization will be provided to interested medicaid providers. A copy of this listing may be obtained by writing to the Department of ~~Social and Rehabilitation~~ Public Health and Human

Services, Medicaid Services ~~Division~~ Bureau, Health Policy and Services Division, ~~111 N. Sanders, P.O. Box 4210, Helena, MT 59604 4210~~ 1400 Broadway, P.O. Box 202951, Helena, MT 59620-2951.

(d) The department hereby adopts and incorporates by reference 42 USC 1396r-8 (1997) as a part of these rules. A copy of 42 USC 1396r-8 (1997) can be obtained by writing to the Department of Public Health and Human Services, Medicaid Services Bureau, Health Policy and Services Division, 1400 Broadway, P.O. Box 202951, Helena, MT 59620-2951.

AUTH: Sec. 53-6-113, MCA
IMP: Sec. 53-6-101, 53-6-113, and 53-6-141, MCA

46.12.703 OUTPATIENT DRUGS, REIMBURSEMENT (1) remains the same.

~~(2) The dispensing fee for filling prescriptions shall be determined for each pharmacy provider annually. The dispensing fee shall include the average sum of the individual provider's direct and indirect costs which can be allocated to the filling of prescriptions, plus an additional sum as an incentive factor, which shall be 7 1/2% of the average of all Montana pharmacy prescription charges for the year the cost survey is conducted. If the individual provider's usual and customary average dispensing fee for filling prescriptions is less than the foregoing method of determining the dispensing fee, then the lesser dispensing fee shall be applied in the computation of the payment to the pharmacy provider. The cost of filling a prescription shall be determined from the Montana dispensing cost survey. A copy of the Montana dispensing cost survey form is available upon request from the department. This Montana dispensing cost survey shall outline the information used in determining the actual average cost of filling a prescription for each pharmacy. A provider's failure to submit the cost survey form properly completed will result in the assignment of the minimum dispensing fee offered. The average cost of filling a prescription will be established on the basis of a determination of all direct and indirect costs that can be allocated to the cost of the prescription department and that of filling a prescription. The dispensing fees assigned shall range between a minimum of $2.00 and a maximum of $4.03. Out-of-state providers will be assigned a $3.50 dispensing fee.~~

(2) The dispensing fee for filling prescriptions shall be determined for each pharmacy provider annually.

(a) The dispensing fee is based on the pharmacy's average cost of filling a prescription. The average cost of filling a prescription will be based on the direct and indirect costs that can be allocated to the cost of the prescription department and that of filling a prescription, as determined from the Montana dispensing fee questionnaire. A provider's failure to submit, upon request, the dispensing fee questionnaire properly completed will result in the assignment of the minimum

dispensing fee offered. A copy of the Montana dispensing fee questionnaire is available upon request from the department.

(b) The dispensing fees assigned shall range between a minimum of $2.00 and a maximum of $4.14.

(c) Out-of-state providers will be assigned a $3.50 dispensing fee.

(d) If the individual provider's usual and customary average dispensing fee for filling prescription is less than the foregoing method of determining the dispensing fee, then the lesser dispensing fee shall be applied in the computation of the payment to the pharmacy provider.

(3) ~~Notwithstanding (2) above, effective July 1, 1990, all in-state pharmacies which became or become providers after November 30, 1986,~~ In-state pharmacy providers that are new to the Montana medicaid program will be assigned an interim $3.50 dispensing fee until a dispensing fee ~~survey~~ questionnaire, as provided ~~for~~ in (2) above, can be completed for 6 months of operation. At that time, a new dispensing fee will be assigned which will be the lower of the dispensing fee calculated in accordance with (2) for the pharmacy or the ~~$4.08~~ $4.14 dispensing fee. Failure to comply with the 6 months dispensing fee ~~survey~~ questionnaire requirement will result in assignment of a dispensing fee of $2.00 ~~being assigned~~.

(4) "Unit dose" prescriptions will be paid by a separate dispensing fee ~~assigned to that pharmacy~~ of $0.75. This "unit dose" dispensing fee will ~~be based upon the average~~ offset the additional cost of packaging supplies and materials which are directly related to filling "unit dose" prescriptions by the individual pharmacy and is in addition to~~, and are documented by each individual pharmacy, plus~~ the regular dispensing fee allowed. Only one unit dose dispensing fee will be allowed each month for ~~prescriptions for chronic conditions~~ each prescribed medication. A dispensing fee will not be paid for a unit dose prescription packaged by the drug manufacturer.

(5) Reimbursement for outpatient drugs provided to medicaid recipients in state institutions shall conform with provisions of the state contract for pharmacy services. Such reimbursement shall not exceed, in the aggregate, reimbursement under (1).

AUTH: Sec. 53-6-113, MCA
IMP: Sec. 53-6-101, 53-6-113 and 53-6-141, MCA

4. The definitions at ARM 46.12.102(19), (20), and (21) apply specifically to outpatient drugs and should therefore be located within subchapter 7, Outpatient Drugs, rather than subchapter 1 which pertains to general requirements of the Medicaid program. Moving the definitions pertaining to outpatient drugs and drug costs from subchapter 1 to subchapter 7 requires the deletion of ARM 46.12.102 (19), (20), and (21) and the adoption of RULE I OUTPATIENT DRUGS, DEFINITIONS.

The definition of maximum allowable cost (MAC) in RULE I has been changed from the version at ARM 46.12.102(20) by deleting "150% of." This deletion is necessary to accurately price MAC drugs. Since the MAC price defined in 42 CFR 447.331 and 447.332 is equal to "150% of" the calculated price, the MAC price cannot be 150% of 150% of the calculated price. To retain the current language would mean that we would overprice MAC drugs in violation of federal rule.

Adopting a definition of "legend drugs" is necessary in Rule I and because the changes in ARM 46.12.702(3) are necessary to convey clearly which drugs will be reimbursed by Medicaid. The phrase "drugs which require a prescription" in ARM 46.12.702(3) is unnecessarily confusing in that Medicaid requires recipients to have prescriptions for all drugs that are reimbursed. The distinction intended in the rule is between legend drugs (drugs that federal law prohibits dispensing without a prescription) and over-the-counter drugs (drugs that federal law allows to be dispensed without a prescription). Medicaid reimburses for very few over-the-counter drugs and those drugs are listed in the department's formulary.

The deletion of "physician" in ARM 46.12.702(5) and (5)(a) is necessary because other licensed practitioners also may prescribe medications and the limitations on dispensing quantity apply regardless of who prescribes. This change is to correct the internal inconsistency in the rule as written which in some parts may be interpreted to limit licensed practitioners who can prescribe drugs.

Limiting the dispensing quantity through reference to "chronic conditions" and "acute conditions" in ARM 46.12.702(5) has been changed because of disputes with pharmacists over the meaning of these terms. Some pharmacists contend that the distinction between chronic and acute conditions is not valid since patients can have acute episodes of chronic diseases. Some pharmacists also argue that prescribers do not indicate on prescriptions whether a drug is for a chronic or acute condition. The proposed rule changes remove the contentious language.

Some aspects of the methodology for determining the provider's dispensing fee described in ARM 46.12.703(2) are now obsolete and have been revised in the proposed rule. For example, when the rule was first written, the cost of filling a prescription was less than the dispensing fee cap and therefore a pharmacy could qualify for an incentive factor of 7.5% of the average of all Montana pharmacy prescription charges for the year. The incentive factor is no longer used because the cost of the filling a prescription is greater than the allowed dispensing fee cap. Therefore, the incentive factor has been deleted in the proposed rule. The current rule also has redundant language. For instance, using the direct and indirect costs of

filling a prescription is mentioned twice within the same rule. The revised language more clearly and succinctly describes the current methodology used in determining the dispensing fee.

The increase in the dispensing fee cap in ARM 46.12.703 to $4.14 is required to implement the 1.5% provider increase allowed for the pharmacy program in the 1997 General Appropriations Act (Chapter 551, Laws of Montana, 1997). The cap increase became effective July 1, 1997 in order to coincide with the state fiscal year.

Deletion of the phrase "prescriptions for chronic conditions" in ARM 46.12.703(4) is required to correspond with changes made to ARM 46.12.702(5). With this change, the pharmacy clearly may not charge the department the additional fee more than once per month even if the medication is dispensed more frequently. The other revisions are required because the unit dose fee is no longer assigned to pharmacies but is paid to any pharmacy which incurs the expense of preparing a unit dose prescription. The department also recognizes that the unit dose fee of $0.75 does not exceed the cost of preparing a unit dose prescription and therefore has removed the documentation requirement. Note that some medications are distributed in unit dose packages by manufacturers and pharmacies are not allowed to charge a unit dose fee for such medications.

The proposed rule change in ARM 46.12.703(5) is necessary because the Medicaid pharmacy program participates in the state's contract for pharmacy services for people in the state institutions. The reimbursement methodology under the state contract differs from the methodology described elsewhere in the rules because the state participates in a multi-state cooperative to buy medications and the state-contracted pharmacy provider is limited to billing the state's cost. Thus, the dispensing fee is the only avenue for the pharmacy provider to recover the cost of providing the service and this fee exceeds the cap set for other pharmacies. Analysis by the department prior to entering into the contract showed that the two reimbursement methodologies resulted in comparable costs to the outpatient drug program.

Other revisions in the proposed rules are necessary to update legal references, dates, and addresses that are no longer valid.

In revising the Medicaid outpatient drug rules, the Department's primary purpose is to implement the 1.5% provider increase passed in the 1997 Montana General Appropriations Act. The Department realized, however, that the current rules had developed over a period of years and included redundant language, outdated references, and provisions that were no longer applicable or caused confusion. Thus, the Department has taken this opportunity to correct these problems. The four

substantive changes in the proposed rules are the provider increase, deletion of the incentive factor in the dispensing fee calculation, deletion of references to acute and chronic conditions, and the adoption of a reimbursement methodology for state-contracted pharmacy services. In making these changes, the Department consulted the Montana Pharmaceutical Association and considered a number of options.

As an alternative, the 1.5% provider increase could have been applied to the product component rather than the dispensing fee. For example, the Department could have altered its method of calculating product cost to pay average wholesale price (AWP) less 8.5%. The decision not to apply the increase in this way was based on several factors. First, federal regulations require that the State pay the estimated acquisition cost of the drug. Studies of the AWP suggest that it overstates pharmacies' acquisition costs by 10 to 20%. Thus, in order to meet federal assurance requirements, the State cannot pay more than AWP less 10%. Second, the current methodology provides an automatic provider increase by paying pharmacies more as drug prices increase. Since the 10% discount does not vary with drug price increases, pharmacies receive a relatively larger reimbursement as prices increase. Third, applying the increase to the dispensing fee provides the most equitable compensation for services since it applies to each prescription dispensed. In this way, the Department ensures that a pharmacy dispensing a low cost generic drug receives a provider increase.

As an alternative to eliminating the incentive factor, the Department could have considered incorporating an incentive factor in the calculation of the dispensing fee in the proposed rule. Since almost all pharmacies already qualify for the dispensing fee cap, however, including an incentive factor would have required a significant increase (more than 1.5%) in the cap. Additionally, the Department realizes that because of the competitive nature of the healthcare marketplace, the proposed dispensing fee is competitive with that paid in other states and by other third-party payers, and no incentive factor is needed to enroll an adequate network of Medicaid pharmacy providers.

Rather than deleting references to acute and chronic conditions, the Department could have adopted operational definitions for these terms. For example, a chronic condition could have been defined as a condition for which the same medication has been prescribed for 90 days. Such a definition would be arbitrary and have no medical basis. It would also assume that the pharmacy knew how long the patient had been on a medication. By expecting the pharmacist to fill a prescription in sufficient quantity to cover the treatment period, the Department is relying on pharmacists' professional requirements which include conferring with prescribers and counseling patients on appropriate drug use.

As an alternative to adopting a different reimbursement methodology for state-contracted pharmacy services, the Medicaid program could have refused to participate in the state contract. Such refusal, however, would have been detrimental to the state institutions and would not have benefitted the Medicaid program. The proposed option recognizes the uniqueness of state institutional providers in comparison with individual pharmacy dispensed drugs to an individual medicaid recipient. The adoption of a different methodology for state institutions is not more costly in the aggregate to the medicaid program.

The changes as proposed will increase payments by an estimated $60,000 per year.

5. Interested persons may submit their data, views or arguments either orally or in writing at the hearing. Written data, views or arguments may also be submitted to Dawn Sliva, Office of Legal Affairs, Department of Public Health and Human Services, P.O. Box 4210, Helena, MT 59604-4210, no later than January 12, 1998. The Department also maintains lists of persons interested in receiving notice of administrative rule changes. These lists are compiled according to subjects or programs of interest. For placement on the mailing list, please write the person at the address above.

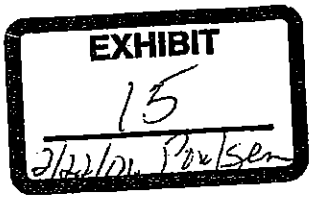
6. The Office of Legal Affairs, Department of Public Health and Human Services has been designated to preside over and conduct the hearing.

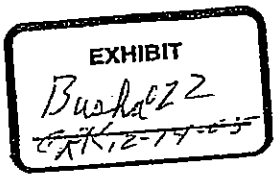
Dawn Sliva
Rule Reviewer

/s/ Dawn Sliva
Director, Public Health and Human Services

Certified to the Secretary of State December 1, 1997.

Exhibit 52





MONTANA

Methods & Standards
for Establishing
Payment Rates,
Services 12 a.,
Outpatient Drug Services

Reimbursement for drugs shall not exceed the lowest of:

1. The Estimated Acquisition Cost (EAC) of the drug plus a dispensing fee, or;

2. The Federal Upper Limit (FUL), Maximum Allowable Cost (MAC) of the drug, in the case of multi-source (generic), plus a dispensing fee, or;

3. The provider's usual and customary charge of the drug to the general public.

Exception: The FUL or MAC limitation shall not apply in a case where a physician certifies in his/her own handwriting the specific brand is medically necessary for a particular recipient. An example of an acceptable certification is the handwritten notation "Brand Necessary" or "Brand Required." A check off box on a form or rubber stamp is not acceptable.

The EAC is established by the state agency using the Federal definition of EAC as a guideline: that is, "Estimated Acquisition Cost" means the state agency's best estimate of what price providers generally pay for a particular drug.

The EAC, which includes single source, brand necessary and drugs other than multi-source, is established using the following methodology:

Drugs paid by their Average Wholesale Price (AWP) will be paid at AWP less 10%. The policy for the reimbursement of Direct Price (DP) drugs (the price charged by manufacturers to retailers) is the current direct price (the direct price in effect on the date of service for the claim.

The MAC for multiple source drugs will not exceed the total of the dispensing fee established by the Department and an amount that is equal to 150 percent of the price established under the methodology set forth in 42 CFR 447.331 and 447.332 for the least costly therapeutic equivalent.

A variable dispensing fee will be established by the state agency, by using the results of a cost survey of pharmacy's operational costs. A pharmacy may be assigned an enhanced dispensing fee to cover the additional costs associated with packaging "unit dose" prescriptions.

Provider dispensing fee(s) are available on-line in the Medicaid Management Information System (MMIS) provider file and in the Medicaid Prescription Drug Card System (PDCS) provider plan file.

TN 95-01
Supersedes TN #88(10)02 Approved 03/27/95 Effective 10/01/94

Exhibit 53

Calculation of Damages and Penalties for the State of Montana

Supplementary Declaration of
Raymond S. Hartman

I. Introduction and Overview

1. My name is Raymond S. Hartman.

2. I have been asked by Counsel to perform a sensitivity analysis to supplement my June 13, 2006 Declaration. The sensitivity analysis allows for the possible effects of data rounding and certain data imprecision when calculating penalties arising from the comparison of Montana Medicaid claims data to statutorily set discounts off AWP. I report the results of this recalculation in Table 7a of this Supplementary Declaration. Table 7a takes Table 7 of my June 13, 2006 Declaration as its point of departure. For ease of exposition, both tables are presented here.

II. The Recalculation of Damages and Recovery of Penalties for False Claims and Deceptive Practices

3. While the assumptions regarding thresholds for the EAC in Tables 3 through 5 of my June 13, 2006 Declaration are reasonable, they are assumptions. In Table 7, I presented supplemental calculations for the number of false and deceptive claims making no assumption regarding EAC. Instead, I counted the number of claims for each type of drug (single-source self-administered, multi-source self-administered and physician-administered) the allowed amount for which exceeded that amount allowed under the Medicaid statute; i.e., AA > AWP – 10% and AA > AWP – 15% for the relevant periods of time. Again, I conducted this analysis only for the claims for which I did not have ASPs and therefore had made (in Tables 3-5) assumptions about the thresholds for EAC.

4. In Table 7 of the June 13, 2006 Declaration, I reported the results of the analysis using a strict application of the statutory language. Specifically, if the allowed amount AA is > AWP – 10% and AA > AWP – 15% for the relevant periods of time, I found the claim false and subject to deceptive trade practices. Using this criterion for the relevant claims (2.42 million in total), I found that 388,628 claims for single-source innovator drugs and 16,280 claims for multi-source drugs exceeded the amount allowed by statute. The total is 404,908. When I included those claims for which I could make a determination by ASP rather than the statutorily-calculated amount, an additional 16,518 claims for single-source innovator drugs and 87,312 claims for multi-source drugs were determined to be false and subject to deceptive trade practices. The total number of claims that were false and subject to deceptive trade practices was 508,738; the total amount of penalties for these claims is $1.53 billion.

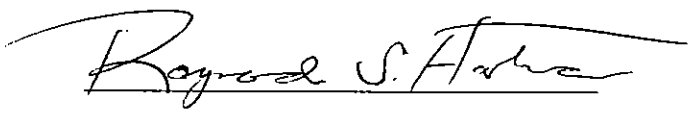
5. The analysis in Table 7 relied upon calculated measures of AWP thresholds and allowed amounts, calculations based upon FDB AWPs which are reported by extended units. Since the allowed amounts on the claims and the AWP thresholds must be expressed in comparable units, rounding to the nearest penny is required for both

components of the comparison. Furthermore, there may be some slight imprecision in the numbers reported. As a result, strict interpretation of the statutory thresholds may suggest an incorrect number of claims as being false and subject to deceptive trade practices. Table 7a provides additional calculations as sensitivity analysis for this possibility.

While I do not analyze systematically the direction of the effect of the rounding and other data issues, I do introduce a calculation that should provide a conservative correction for these data issues. Specifically, I allow for an extra percentage point in the statutory threshold using AWP; that is, if the allowed amount AA is > AWP – 9% and AA > AWP – 14% for the relevant periods of time, I find the claim false and subject to deceptive trade practices.

Using these criteria for those claims (again 2.42 million in total) for which I use these more liberal (to Defendants) thresholds, I find that 8,527 claims for single-source innovator drugs and 922 claims for multi-source drugs exceed the threshold. The total is 9,449. When I include those claims for which I can make a determination based on ASP rather than the statutorily-calculated amount, the additional number of claims does not change; 16,518 claims for single-source innovator drugs and 87,312 claims for multi-source drugs are determined to be false and subject to deceptive trade practices. In this case, the total number of claims that are false and subject to deceptive trade practices is 113,279; the total amount of penalties for these claims is $340 million.

I declare that this declaration is true and correct.



June 20, 2006

Table 7: Deceptive Trade and False Claims Penalties - Innovator and Multi-Source Drugs (Statute Change)

		Analysis Using ASP			*Analysis Using AWP Statute*			*Innovator Penalties (ASP and Statute Change in July 2002 from AWP - 10% to AWP - 15%)*			*Multi-Source Penalties (ASP and Statute Change in July 2002 from AWP - 10% to AWP - 15%)*			*Total Statute Penalties*
	Total # of Claims	# of Claims Used in ASP Analysis[1]	# of Fraudulent Claims (Innovator)[2]	# of Fraudulent Claims (Multi-Source)[3]	# of Claims Used in AWP Statute Analysis[4]	# of Innovator Fraudulent Claims Based on Statute (10%-15%)[5]	# of Multi-Source Fraudulent Claims Based on Statute (10%-15%)[6]	Deceptive Trade ($1000/claim)	False Claim ($2000/claim)	Total Penalties	Deceptive Trade ($1000/claim)	False Claim ($2000/claim)	Total Penalties	Total Penalties
Abbott	59,602	0	0	0	59,602	1,327	1,500	$1,327,000	$2,654,000	$3,981,000	$1,500,000	$3,000,000	$4,500,000	$8,481,000
Amgen	7,037	0	0	0	7,037	1,129	35	$1,129,000	$2,258,000	$3,387,000	$35,000	$70,000	$105,000	$3,492,000
AstraZeneca	224,628	5,316	5,117	0	219,312	25,284	0	$30,401,000	$60,802,000	$91,203,000	$0	$0	$0	$91,203,000
Aventis Group	132,015	161	157	0	131,854	29,368	0	$29,525,000	$59,050,000	$88,575,000	$0	$0	$0	$88,575,000
Baxter	5,644	0	0	0	5,644	54	1,134	$54,000	$108,000	$162,000	$1,134,000	$2,268,000	$3,402,000	$3,564,000
Bayer	47,582	0	0	0	47,582	10,685	0	$10,685,000	$21,370,000	$32,055,000	$0	$0	$0	$32,055,000
Boehringer Group	15	0	0	0	15	0	1	$0	$0	$0	$1,000	$2,000	$3,000	$3,000
Braun	3,320	0	0	0	3,320	0	852	$0	$0	$0	$852,000	$1,704,000	$2,556,000	$2,556,000
BMS Group	330,533	645	626	0	329,888	69,762	0	$70,388,000	$140,776,000	$211,164,000	$0	$0	$0	$211,164,000
Dey	51,373	0	0	0	51,373	0	8,892	$0	$0	$0	$8,892,000	$17,784,000	$26,676,000	$26,676,000
Fujisawa Group	1,535	0	0	0	1,535	285	3	$285,000	$570,000	$855,000	$3,000	$6,000	$9,000	$864,000
Immunex	46	0	0	0	46	16	0	$16,000	$32,000	$48,000	$0	$0	$0	$48,000
Johnson & Johnson	352,973	1,879	997	836	351,094	66,134	667	$67,131,000	$134,262,000	$201,393,000	$1,503,000	$3,006,000	$4,509,000	$205,902,000
Novartis	248,835	0	0	0	248,835	59,344	284	$59,344,000	$118,688,000	$178,032,000	$284,000	$568,000	$852,000	$178,884,000
Pfizer	655,962	0	0	0	655,962	88,598	81	$88,598,000	$177,196,000	$265,794,000	$81,000	$162,000	$243,000	$266,037,000
Pharmacia Group	40,181	20	12	5	40,161	5,912	6	$5,924,000	$11,848,000	$17,772,000	$11,000	$22,000	$33,000	$17,805,000
Schering-Plough Group	242,263	96,886	9,609	86,471	145,377	18,061	2,533	$27,670,000	$55,340,000	$83,010,000	$89,004,000	$178,008,000	$267,012,000	$350,022,000
Sicor Group	5	0	0	0	5	0	0	$0	$0	$0	$0	$0	$0	$0
TAP	78,278	0	0	0	78,278	12,669	0	$12,669,000	$25,338,000	$38,007,000	$0	$0	$0	$38,007,000
Watson	41,361	0	0	0	41,361	0	292	$0	$0	$0	$292,000	$584,000	$876,000	$876,000
Total-All Defendants	2,523,188	104,907	16,518	87,312	2,418,281	388,628	16,280	$405,146,000	$810,292,000	$1,215,438,000	$103,592,000	$207,184,000	$310,776,000	$1,526,214,000

Notes:
1. Tables 3, 4 and 5.
2. Tables 3 and 5.
3. Table 4.
4. Tables 3, 4 and 5.
5. Table 3. These Totals also include the number of fraudulent claims calculated from the Medical claims data, based on the same statutory thresholds.
6. Table 4.

Table 7a: Deceptive Trade and False Claims Penalties - Innovator and Multi-Source Drugs (Adjusting for Rounding and Data Issues - Assume Statute Allows AWP - 9% and AWP - 14%)

		Analysis Using ASP			*Analysis Using AWP Statute*			*Innovator Penalties (ASP and Statute Change in July 2002 from AWP - 9% to AWP - 14%)*			*Multi-Source Penalties (ASP and Statute Change in July 2002 from AWP - 19% to AWP - 14%)*			*Total Statute Penalties*
	Total # of Claims	# of Claims Used in ASP Analysis[1]	# of Fraudulent Claims (Innovator)[2]	# of Fraudulent Claims (Multi-Source)[3]	# of Claims Used in AWP Statute Analysis[4]	# of Innovator Fraudulent Claims Based on Statute (9%-14%)[5]	# of Multi-Source Fraudulent Claims Based on Statute (9%-14%)[6]	Deceptive Trade ($1000/claim)	False Claim ($2000/claim)	Total Penalties	Deceptive Trade ($1000/claim)	False Claim ($2000/claim)	Total Penalties	Total Penalties
Abbott	59,602	0	0	0	59,602	115	202	$115,000	$230,000	$345,000	$202,000	$404,000	$606,000	$951,000
Amgen	7,037	0	0	0	7,037	12	0	$12,000	$24,000	$36,000	$0	$0	$0	$36,000
AstraZeneca	224,628	5,316	5,117	0	219,312	934	0	$6,051,000	$12,102,000	$18,153,000	$0	$0	$0	$18,153,000
Aventis Group	132,015	161	157	0	131,854	1,552	0	$1,709,000	$3,418,000	$5,127,000	$0	$0	$0	$5,127,000
Baxter	5,644	0	0	0	5,644	0	272	$0	$0	$0	$272,000	$544,000	$816,000	$816,000
Bayer	47,582	0	0	0	47,582	29	0	$29,000	$58,000	$87,000	$0	$0	$0	$87,000
Boehringer Group	15	0	0	0	15	0	0	$0	$0	$0	$0	$0	$0	$0
Braun	3,320	0	0	0	3,320	0	58	$0	$0	$0	$58,000	$116,000	$174,000	$174,000
BMS Group	330,533	645	626	0	329,888	360	0	$986,000	$1,972,000	$2,958,000	$0	$0	$0	$2,958,000
Dey	51,373	0	0	0	51,373	0	14	$0	$0	$0	$14,000	$28,000	$42,000	$42,000
Fujisawa Group	1,535	0	0	0	1,535	3	0	$3,000	$6,000	$9,000	$0	$0	$0	$9,000
Immunex	46	0	0	0	46	11	0	$11,000	$22,000	$33,000	$0	$0	$0	$33,000
Johnson & Johnson	352,973	1,879	997	836	351,094	1,455	193	$2,452,000	$4,904,000	$7,356,000	$1,029,000	$2,058,000	$3,087,000	$10,443,000
Novartis	248,835	0	0	0	248,835	41	0	$41,000	$82,000	$123,000	$0	$0	$0	$123,000
Pfizer	655,962	0	0	0	655,962	3,998	0	$3,998,000	$7,996,000	$11,994,000	$0	$0	$0	$11,994,000
Pharmacia Group	40,181	20	12	5	40,161	11	0	$23,000	$46,000	$69,000	$5,000	$10,000	$15,000	$84,000
Schering-Plough Group	242,263	96,886	9,609	86,471	145,377	6	0	$9,615,000	$19,230,000	$28,845,000	$86,471,000	$172,942,000	$259,413,000	$288,258,000
Sicor Group	5	0	0	0	5	0	0	$0	$0	$0	$0	$0	$0	$0
TAP	78,278	0	0	0	78,278	0	0	$0	$0	$0	$0	$0	$0	$0
Watson	41,361	0	0	0	41,361	0	183	$0	$0	$0	$183,000	$366,000	$549,000	$549,000
Total-All Defendants	2,523,188	104,907	16,518	87,312	2,418,281	8,527	922	$25,045,000	$50,090,000	$75,135,000	$88,234,000	$176,468,000	$264,702,000	$339,837,000

Notes:
1. Tables 3, 4 and 5.
2. Tables 3 and 5.
3. Table 4.
4. Tables 3, 4 and 5.
5. Table 3. These Totals also include the number of fraudulent claims calculated from the Medical claims data, based on the same statutory thresholds.
6. Table 4.

Exhibit 54

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In Re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456**
THIS DOCUMENT RELATES TO:	**Master File No. 01-CV-12257-PBS**
State of Montana v. Abbott Laboratories, Inc. et al., D Mont. Cause No. CV-02-09-H-DWM	**Judge Patti B. Saris**

DEY, INC.'S ANSWER TO THE STATE OF MONTANA'S SECOND AMENDED COMPLAINT

Defendant Dey, Inc. ("Dey"), by its attorneys, Kelley Drye & Warren LLP, for its Answer to the State of Montana's Second Amended Complaint (the "Complaint"), states:

1. Dey denies the allegations in Paragraph 1 of the Complaint, except admits that Plaintiff purports to bring this action as alleged in Paragraph 1 of the Complaint.

2. Insofar as the allegations in the first sentence of Paragraph 2 of the Complaint are directed at Dey, Dey admits those allegations, except denies that Dey marketed to purchasers in the State of Montana. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in the remainder of Paragraph 2 and, therefore, denies those allegations.

3. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3 of the Complaint and, therefore, denies those allegations.

388. Dey denies the allegations in Paragraph 388 of the Complaint, except admits that it reported certain pricing information for its drugs to pharmaceutical industry pricing publications and that it reported suggested AWP prices, and further admits that it prepared the document Bates stamped DL-CA 00120, cited in Paragraph 388 of the Complaint, but Dey states that this document is the best evidence of its contents and denies that the conclusions that the State draws from this document are accurate. Dey denies that it prepared the document Bates stamped DL-CA 00080, cited in Paragraph 388 of the Complaint, except Dey admits that the referenced, handwritten notations on DL-CA 00080 were made by a Dey employee.

389. Dey denies the allegations in Paragraph 389 of the Complaint, and refers the Court to the complaint cited in Paragraph 389 as the best evidence of its contents.

390. Dey denies the allegations in Paragraph 390 of the Complaint.

391. Dey denies the allegations in Paragraph 391 of the Complaint.

392. Dey denies the allegations in Paragraph 392 of the Complaint, except admits that it prepared the documents cited in Paragraph 392 of the Complaint (DL-TX-0090852 and DL-TX-0090854) but states that these documents are the best evidence of their contents and denies that the conclusions the State draws from these documents, if any, are accurate.

393-394. Dey denies the allegations in Paragraphs 393 and 394 of the Complaint, except admits that it prepared the documents cited in Paragraphs 393 and 394 of the Complaint (DL-TX-0014029 and DL-TX-0014439) but states that these documents are the best evidence of their contents and denies that the conclusions the State draws from these documents are accurate.

395-397. To the extent that the allegations in Paragraphs 395 through 397 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth

Exhibit 55

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL 1456 Master File No. 01-CV-12257-PBS Judge Patti B. Saris
THIS DOCUMENTS RELATES TO: *State of Montana v. Abbott Labs., Inc., et al.*, No. CV-02-09-H-DWM	

IMMUNEX CORPORATION'S ANSWER TO STATE OF MONTANA'S SECOND AMENDED COMPLAINT

Defendant Immunex Corporation ("Immunex") answers the Second Amended Complaint ("SAC"), dated as of August 1, 2003, as follows:

The SAC improperly and repetitively refers to Immunex and other defendants and third parties on a collective basis, failing to plead with requisite particularity allegations against Immunex.

Immunex was acquired by defendant Amgen during this litigation but remains separately incorporated. Immunex is not responsible for the actions of Amgen, and Amgen is not responsible for the actions of Immunex. Amgen has assumed the marketing of Enbrel, and it will answer as to Enbrel and all related activities.

Intentionally ambiguous pleading is improper and insufficient to apprise Immunex in any meaningful sense of the allegations asserted against it. Immunex has nevertheless attempted to respond to the State's allegations to the extent possible under the

allegations are directed at Immunex and require a response, Immunex denies those allegations.

5 – 6. Immunex admits that certain medicines are covered under Medicare Part B, and that during certain times Congress mandated that Medicare Part B reimbursement be based upon AWP, an industry practice and term of art incorporated by the government as a reimbursement benchmark, and that Medicare Part B medicines are generally administered in a healthcare provider's office. Immunex admits that it reports some pricing information for its medicines to independent pharmaceutical industry publications. Immunex admits that AWP benchmarks published in trade publications can be higher than the prices ultimately paid by providers. Immunex denies the existence of, and its participation in, any "AWP scheme" or "unlawful agreement" as alleged in Paragraph 6. Except as specifically admitted and to the extent that any remaining allegations are directed at Immunex, Immunex denies those allegations in Paragraphs 5 – 6.

7. Immunex denies the existence of, and its participation in, any "AWP scheme" or "AWP Inflation Scheme" as alleged in Paragraph 7. Immunex denies that it "fraudulently reports" its drugs on a "fictitious and fraudulent AWP." To the extent that the remaining allegations in Paragraph 7 are directed at Immunex, Immunex denies those allegations.

8. Immunex admits that certain medicines are covered under Medicare Part B, and that during certain times Congress mandated that Medicare Part B reimbursement be based upon AWP, an industry practice and term of art incorporated by the government as a reimbursement benchmark, and that Medicare Part B medicines are generally administered in a healthcare provider's office. Immunex admits that AWP benchmarks published in trade publications can be higher than the prices ultimately paid by providers. Immunex denies that it has engaged "secret profits" or "inflated AWP schemes" as alleged in Paragraph 8.

Exhibit 56

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
	Civil Action No. 01-CV-12257-PBS
THIS DOCUMENT RELATES TO:	Judge Patti B. Saris
State of Montana v. Abbott Labs., Inc., et al., D. Mont. Cause No. CV-02-09-H-DWM	

SCHERING-PLOUGH CORPORATION'S ANSWER TO THE STATE OF MONTANA'S SECOND AMENDED COMPLAINT

Schering-Plough Corporation ("Schering-Plough") answers the State of Montana's Second Amended Complaint ("Amended Complaint") as follows:

1. The allegations in paragraph 1 state legal conclusions as to which no answer is required. To the extent that an answer is required, Schering-Plough denies the allegations in paragraph 1.

2. Schering-Plough admits that it is a manufacturer of pharmaceutical products. To the extent the allegations of this Paragraph refer to statutory or regulatory programs, the statutes, regulations and other sources regarding those programs speak for themselves. To the extent that the allegations in paragraph 2 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 2. Schering-Plough denies the remaining allegations in paragraph 2.

3. The allegations in paragraph 3 state legal conclusions as to which no answer is required. To the extent that an answer is required, Schering-Plough denies the allegations in paragraph 3.

4. The allegations in paragraph 4 state legal conclusions as to which no answer is required. To the extent that an answer is required, Schering-Plough denies the allegations in paragraph 4.

5. To the extent that the allegations in paragraph 5 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 5. Schering-Plough denies the remaining allegations in paragraph 5.

6. To the extent that the allegations in paragraph 6 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 6. Schering-Plough admits that it reports certain pricing information for its medicines to pharmaceutical industry pricing publications. Schering-Plough denies the remaining allegations in paragraph 6.

7. To the extent that the allegations in paragraph 7 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 7. Schering-Plough denies the remaining allegations in paragraph 7.

8. To the extent that the allegations in paragraph 8 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 8. Schering-Plough denies the remaining allegations in paragraph 8.

213. Schering-Plough admits that the DOJ and the OIG have been investigating Schering-Plough, among others, for practices relating to the calculation of AWP. Schering-Plough further admits that the United States House of Representatives Committee on Commerce has made requests for documents and information relating to AWP, to which Schering-Plough has responded. To the extent that the allegations in paragraph 213 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 213. Schering-Plough otherwise denies the remaining allegations in paragraph 213.

214-215. To the extent that the allegations in paragraphs 214 through 215 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraphs 214 through 215. Schering-Plough otherwise denies the remaining allegations in paragraphs 214 through 215.

216-531. The allegations contained in paragraphs 216 through 531 refer to parties other than Schering-Plough. To the extent the allegations contained in paragraphs 216 through 531 are deemed to include allegations against Schering-Plough, Schering-Plough denies the allegations.

532. Schering-Plough denies the allegations contained in paragraph 532.

533. Schering-Plough denies the allegations contained in paragraph 533.

534. Schering-Plough admits that it communicates with industry compendia concerning AWP for its products. Schering-Plough avers that the document referenced in the second sentence of paragraph 534 speaks for itself. Schering-Plough denies the remaining allegations in paragraph 534.

535. Schering-Plough denies the allegations contained in paragraph 535.

Exhibit 57

UNITED STATES DISTRICT COURT FOR

THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 CIVIL ACTION: 01-CV-12257-PBS Judge Patti B. Saris
THIS DOCUMENT RELATES TO: *State of Montana v. Abbott Labs., Inc., et al.*, D. Mont. Cause No. CV-02-09-H-DWM	

DEFENDANT TAP PHARMACEUTICAL PRODUCTS INC.'S ANSWER AND DEFENSES TO STATE OF MONTANA'S SECOND AMENDED COMPLAINT

Defendant TAP Pharmaceutical Products Inc. ("TAP") hereby responds to the State of Montana's Second Amended Complaint (the "Complaint") in corresponding numbered paragraphs as follows:

Preface

The Complaint improperly and repetitively refers to TAP and certain other defendants and third parties on a collective basis, failing to plead with requisite particularity allegations against TAP or other defendants or third parties. Intentionally ambiguous pleading is improper and insufficient to apprise TAP in any meaningful sense of the allegations asserted against it. TAP nevertheless attempts to respond to Plaintiff's allegations to the extent possible under the circumstances. In answering the Complaint, TAP responds only for itself, even when Plaintiff's allegations refer to alleged conduct by TAP and other persons or entities. To the extent the allegations in the Complaint refer to the knowledge, conduct or actions of persons, entities or

These comments and objections are incorporated, to the extent appropriate, into each numbered paragraph of this Answer.

I.

1. TAP admits that Plaintiff seeks to bring this action as alleged in Paragraph 1 of the Complaint. TAP denies that Plaintiff is entitled to maintain this action in the manner alleged. TAP denies the remaining allegations in Paragraph 1 of the Complaint.

2. To the extent the allegations in Paragraph 2 of the Complaint refer to statutory or regulatory programs, the statutes, regulations and other sources regarding those programs establish their contents, and any characterizations thereof are denied. TAP denies the remaining allegations in Paragraph 2 of the Complaint.

3-4. The allegations in Paragraphs 3 and 4 of the Complaint contain Plaintiff's generalizations and self-serving conclusions to which no response is required. To the extent a response is required, TAP denies the allegations in Paragraphs 3 and 4 of the Complaint and strict proof is demanded thereof.

5. TAP admits that Congress mandated that Medicare Part B reimbursement be based, in part, in certain circumstances, on AWP and that certain Medicaid programs and private insurance companies reimburse drugs based, in part, in certain circumstances, on AWP. TAP denies the remaining allegations in Paragraph 5 of the Complaint.

6-10. Denied.

11-12. The Court dismissed Plaintiff's "Best Price" claims in its Order dated June 10, 2004. Accordingly, TAP does not respond to Paragraphs 11 through 12 of the Complaint.

13-17. Denied.